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#### Medical Recourse :

A male aged about 42 years was having difficulty in walking due to pain & discomfort in legs and was under treatment since 1990, with past history of trauma in 1983. On 13.04.1998, he was diagnosed to have “mild hepatomegaly with aneurysm of lower abdominal aorta just above bifurcation” by colour doppler examination and was advised “Urgent Surgical Repair”. On 22.04.1998, patient was operated by appellant doctor/s at B Hospital for “Surgical dissection of aneurysm & PTFE Y limb Graft” and placed on ventilator in recovery room. Same day patient was found not to have pulse in legs which were cold. DSA was advised to evaluate post operative status and angiography which showed “block (clot) at graft” and patient was re-explored on same day and “fresh graft suturing” was undertaken. On 27.05.1998 patient was diagnosed have developed wet gangrene and on 29.05.1998, B/L Guillotine Amputation was undertaken. Subsequently patient was diagnosed with septicemia on 30.05.1998 and due to septic shock unfortunately breathed his last on 12.06.1998 at the same hospital.

#### Legal Recourse:

Hon’ble National Consumer Dispute Redressal Commission awarded compensation of Rs. 14,18,491 along with 9% interest rate per annum. An article “Repair of Infra renal Abdominal Aortic Aneurysm” related to mortalities related to such repair. Text book by “Robert B Rutherford” were referred by Hon’ble commission in addition to judgement – “Whitehouse V Jordan & Anr” for doctrine of “Res Ipsa Loquitur”.

Vide above referred appeal, appellant approached Hon’ble Supreme Court and major / important aspects are summarised:

#### 1) Letters in spirit -in Major Averages by Parties to the dispute

Sr No	Complainant	Appellant/s
A	The Doctor had not examined the patient after surgery	“The patient was in critical condition when the Doctor was consulted on 21.4.1998 and surgery was thereafter performed within two days.” Treating doctor and subordinate doctors attended patient post operatively for monitoring and modality, as required.
B	The patient was made to stand in queue for DSA test despite his critical condition whereafter the machine was found to be dysfunctional	Non-working of the DSA machine and consequent delay in performing the test cannot be said to be negligence on the part of the Doctor or the Hospital. The DSA machine is a large, expensive and complicated machine which unfortunately developed certain technical problem at the time when patient had to be tested. Any machine can become non-functional because of innumerable factors beyond the human control as the machines involve various mechanical, electrical and electronic components.
C	Angiography was performed after 8 hours of discovering that blood supply has stopped;	Operation theatres cannot be presumed to be available at all times. Therefore, non-availability of an emergency operation theatre during the period when surgeries were being performed on other patients is not a valid ground to hold the Hospital negligent in any manner.
D	The Hospital delayed treatment by 12 hours as no operation theatre was available	-do-
E	The Doctor did not attend the patient and left him in the care of inexperienced doctors	As per the stand of the Hospital and the Doctor, the patient was kept in Cardio Vascular Intensive Care Unit after the surgery and was continuously being monitored by qualified post-graduate doctors.
F	Doctor failed to amputate legs on time on account of gangrene and did not try to treat the gangrene	on 27.5.1998 and observed that the patient had wet gangrene below knee and was thus advised amputation. On 29.5.1998, the patient was operated for amputation below the knee at the level of tibial tuberosity for treatment of wet gangrene and the Bilateral Guillotine Amputation was carried out.
G	The reliance on the principle of res ipsa loquitur to support the finding that it is a case of medical negligence.	Simply because a patient has not favourably responded to a treatment given by a doctor or a surgery has failed, the doctor cannot be held straightaway liable for medical negligence by applying the doctrine of res ipsa loquitur. The said allegations are not based or supported on the basis of the independent expert’s opinion.

#### 2) Salient Features of Judgement by Hon’ble Supreme Court

“simply because the patient has not favourably responded to a treatment given by doctor or a surgery has failed, the doctor cannot be held straight away liable for medical negligence by applying the doctrine of Res Ipsa Loquitur.”

“Having noted the decisions relied upon by the learned counsel for the parties, it is clear that in every case where the treatment is not successful or the patient dies during surgery, it cannot be automatically assumed that the medical professional was negligent. To indicate negligence there should be material available on record or else appropriate medical evidence should be tendered.”

“we find that the findings recorded by the Commission holding the Hospital and the Doctor guilty of medical negligence are not sustainable in law. Consequently, the present appeals are allowed. The order passed by the Commission is set aside and the complaint is dismissed.”



## EDITORIAL

# Conflict in laboratory medicine

**Mahanta Putul\***

The activities in laboratory establishment are screened by various moral, ethical and legal principles. The primary issues are informed consent, the privacy of the patient and their records, codes of conduct, conflict of interest, laboratory utilization, skill, and direct access testing. These issues are ethically challenging in the ordinary set-up in developing countries like India. The interpretation of the laboratory report and authentication of the same by signatures plays a significant role in diagnosing and managing the patient in the era of evidence-based medicine (EBM).

Recently, several violations of those guidelines by medical professionals with laboratory medicine have been reported around the globe.

**Case report<sup>1</sup>:** *In a complaint to Maharashtra Medical Council (MMC) Mumbai, Dr Prasad Kulkarni identified Dr Sireesha Mohan, a pathologist & Microbiologist. She has multiple connections with private pathology labs located at various places, which makes it impossible for any individual to visit daily. Also, her name and signature is being used for insurance claims and used to allow her scan signature to the pathology labs. MMC has conducted an inquiry and found her guilty and have removed her registration number from the council's register for six months.*

Many other reported cases of violating the existing code of conduct need well-reformed ethical and legal guidelines to curb professional misconduct.

Within the limited resources, the laboratory medicine field contributes a lot in removing the pain and agony from the suffering people of rural India. Therefore, ethics come into force while choosing the services to the patient.

Another aspect is the staff member working in the laboratory. The code of conduct, professionalism, skill hand and good communication of those workers play a lot in delivering prompt services at the needy hours. So, the laboratory staff's perception, knowledge, and attitudes regarding the moral, ethical, and legal issues with the laboratory practice are essential.

Maintaining the lab record and privacy practice is also of paramount importance. The safety measures of the operational staff from biohazard and bio-medical waste management are critical issues.

Therefore, it is exceedingly proposed that understanding ethics helps protect confidence, functional integrity, capability, impartiality, and staff safety. Numerous scientific organizations have developed operational Standard Operating Procedures (SOP) regarding handling ethical issues in those establishments. The defined ethical

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recommendations for clinical laboratories have been developed by the International federation of clinical chemistry (IFCC), the American Association of Clinical Chemistry (AACC) and the International Organization for Standardization (ISO). Those organizations have outlined the responsibilities of laboratory professionals towards their patients, profession and society. Though ethical standards and guidelines vary, the basic principles of ethics are the same to be followed.

Further, with changes occurring in the societal attitude and raw consumerism, each patient should be considered a potential litigant, especially when health care has been declared a service industry that breaks the bond, respect, and trust among the physician and patient. Hence, it is mandatory to incorporate bioethics' core principles and regulations in laboratory institutes.

The laboratory establishment and research involving humans as participants are interconnected by laboratory testing. The issues of handling new results left out biological samples, and genetic testing are governed by many regulations, and those establishments should follow international ethical principles and procedures.

In India, it is mandatory to follow Indian Council of Medical Research (ICMR) guidelines while research is initiated with biological samples or humans as a research participants. The practices in laboratory medicine should be limited defined by law, SOPs and must defend the highest code of conduct in their profession.

The cost of malpractice claims is considerable, both monetarily and impacting the healthcare system. Wary of possible lawsuits, many physicians have closed their practices, stopped performing high-risk procedures, or reduced their care of high-risk patients leading to a situation in which some areas of the country have limited or even no access to medical specialists or critical laboratory facilities.

Turning face to another side, are you ready to face the consequences of poorly trained and skilled health care professionals?

The management should guarantee that no activities that would weaken trust in the lab competence, impartiality, judgment, or functional integrity should be allowed. The administration and professional working should be free from any unwarranted profit-making, financial or other burdens and pressures that may negatively affect the quality of their work. Conflict of interest should be publicly declared, if any. Follow the proper methods to ensure that staff treat human samples left out as per the appropriate guidelines. The maintenance of privacy of the patient and their lab record should also be secured to avoid any unnecessary conflict.

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### RESEARCH PAPER

# Clinical profile of palliative care Patient at the state cancer institute of a North-eastern state of India: a cross-sectional study

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**Background and aims:** With the patient's limited scope to palliative care in India's North-eastern state, this service has been a decade since it was available. The people of this region are unaware of this department's role at the State Cancer Institute (SCI) to promote life with a debilitating illness from diagnosis to death. Palliative care is one of the essential components of cancer care which has lots of ethical and legal issues and has been present in India for decades now but still limited data regarding palliative care from India's North-Eastern state. Therefore, we aimed to study the clinical profile of cancer patients in the palliative setting. **Material and Methods:** The present study was a cross-sectional study on patients attending the outpatient department (OPD) of the pain and palliative care of SCI, Gauhati Medical College and Hospital (GMCH), Guwahati, for twelve months from January 2020 to December 2020. In the study, we recorded the patient's age, sex, performance status, symptomatology and primary diagnosis during their visit to the pain and palliative care department. The data were analyzed using SPSS version 22. The ethical clearance was taken from the "Institutional Ethics Committee" of SCI of GMCH, Guwahati, Assam and India. Informed consent was also taken from the participating patient. **Results:** A total of 1002 cancer patients were included in the study. The median age of presentation was 41.5 years (range 18-86 years). The male and female ratio was 1:1.12. The majority, 443 out of 1002 patients, had Eastern Cooperative Oncology Group (ECOG) Performance Status (PS)-2, followed by ECOG PS-3 (32.2%) with 323 patients. Overall, head and neck cancer were the most common cancer (20.6%) with 206 patients, followed by 162 patients with carcinoma gall bladder (16.2%) and 132 patients with oesophageal cancer (13.2%), while in female, breast cancer was the most common and out of 101 breast cancer cases 97 were females. In the symptomatology, the pain was the most common symptom (82.1%), followed by anorexia (73.2%) and generalized weakness (66.7%). Most of the patients (45.9%) were assessed with severe pain. Skeleton was the most common site of metastasis (49.7%), followed by lung (24.1%) and liver (17.2%). Most patients attending the pain and palliative OPD were in stage IV (n=581, 58%), followed by Stage III (n=290, 29%) cancer. **Conclusion:** Pain was the most common symptom that adversely affects cancer patients' quality of life. Therefore, an early referral for palliative care needs to be ensured.

**Keywords:** Pain relief; terminally ill; clinical profile, quality of life.

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## INTRODUCTION

The World Health Organization (WHO) defines palliative care as “an approach that improves the quality of life of patients and their families facing the problem associated with a life-threatening illness, through the prevention and relief of suffering utilizing early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.”<sup>1</sup> This care is required by patients suffering from various chronic diseases but has been most commonly used for cancer patients.<sup>2</sup> The concept of palliative care existed far back in history. Still, Dame Cicely Saunders has popularized the idea of modern palliative care with the setup of St Christopher’s hospices in 1967 for end-of-life care.<sup>3</sup> Now, palliative care has broadened from diagnosis to beyond grief for the family.<sup>4</sup> In India, palliative care is still an emerging discipline.<sup>5</sup>

India has a high load of cancer patients. According to the estimates of the National Cancer Registry Programme Report 2020, released by the Indian Council of Medical Research (ICMR) in association with the National Centre for Disease Informatics and Research (NCDIR) Bengaluru, there will be about 1.39 million cancer cases in 2020, which is likely to increase to 1.57 million by 2025, based on current trends. There will be an estimated 12% rise in cancer cases in India in the next five years. While the need for palliative care is high in India, carrying many ethical and legal issues, there is minimal data on patients opting for palliative care in India. SCI, Guwahati, is one of India’s North-Eastern region’s tertiary care oncology centres, providing comprehensive oncology services to patients from entire North-Eastern areas. Thereby, we aimed to evaluate patients’ clinical profile attending the pain and palliative care OPD at SCI of GMCH.

## MATERIAL AND METHODS

The present study is a hospital-based cross-sectional study on 1002 patients who had attended the OPD of pain and palliative care at SCI of GMCH, Guwahati, for palliative care for 12 months from January 2020 to December 2020. The study included all patients of age more than 18 years attending OPD of pain and palliative care at the referral hospital with a confirmed cancer diagnosis. During their visit to the pain and palliative care department, the patient’s clinical profile like age, sex, marital status, performance status, and primary diagnosis of the type of cancer, symptomatology, stage of cancer, and metastasis site, were recorded on a questionnaire developed by the researchers. To study the symptomatology of the cancer patients included in the study, a checklist of 32 symptoms was included in the questionnaire. The symptoms were assessed as per the patients’ self-reporting during their visit to pain and palliative care OPD. As all symptoms reported by the patient were recorded therefore multiple counts of symptoms per patient were possible.

The patient’s performance status was assessed using the ECOG PS<sup>6</sup> scale, which measures their level of functioning in their daily living abilities and physical activities with scores ranging from 0 to 5. The ECOG-PS scale was first published in 1982 and developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group.

Assessment of pain is essential for effective pain management. Various one-dimensional tools such as numerical pain intensity scale and visual analogue scale have been commonly used to assess the pain intensity at rest and during movement.<sup>7</sup> In the present study, pain intensity among the study participants was assessed using a numerical rating scale (NRS) ranging from 0-10. The numerical pain scores assigned were 0: No pain, 1-3: Mild pain, 4-7: Moderate pain and 8-10: Severe pain.

The data were analyzed using the Statistical Package for the Social Studies (SPSS) version 22 (IBM Corp., Armonk, New York). The ethical clearance was taken from the “Institutional Ethics Committee” of SCI of GMCH, Guwahati, Assam, and India vide ref: SCI/ECR/2020/16 dated 02/05/2020 before collecting the data. Informed consent was obtained from the study participants, and that the guidelines outlined in the declaration of Helsinki were followed.

## RESULTS

The median age of presentation was 41.5 years (range 18 to 86 years). In the study, most patients were female, with a male and female ratio of 1:1.12. Twenty-one patients (2.1%) were unmarried. About 69.6% of patients were female in the 41-50 years age group, and 61.8% were male. The majority of patients attending pain and palliative OPD had an ECOG PS-2 (44.2%) followed by ECOG PS-3 (32.2%), as shown in **Table 1**.

**Table 1** Clinical characteristics of palliative care patients

Sl.No.	Parameters	Number (%)
1.	Total number of patients included	1002
2.	Age of presentation in years	41.50years (range, 18-86)
3.	Sex: Male Female	472(47.1%) 530(52.9%)
4.	Marital status Married Unmarried	981(97.9%) 21(2.1%)
5.	ECOG PS: PS- 0 PS- 1 PS- 2 PS- 3 PS- 4	50(5.0%) 125(12.5%) 443(44.2%) 323(32.2%) 61(6.1%)

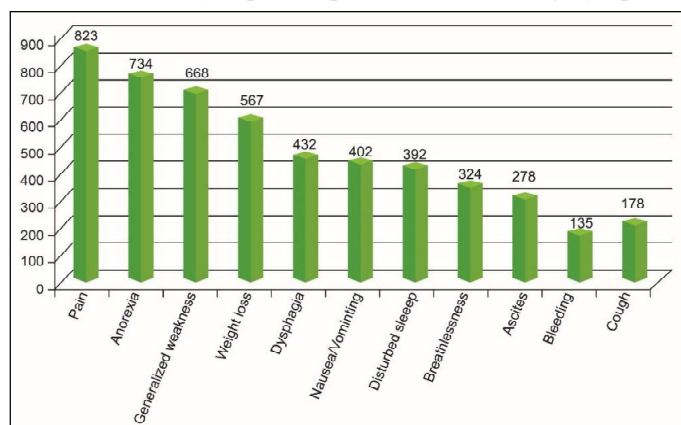


In the study, we have found that overall, patients with head and neck cancer like oral carcinoma cavity, oropharynx, larynx attended to our OPD for palliation of their symptoms in maximum number followed by the carcinoma gall bladder, oesophagus, breast, lung and others. Head and neck cancer was the most common cancer in males gender-wise, followed by oesophageal, gall bladder, and lung cancer. Female breast cancer was the most common, followed by the gall bladder and gynaecological cancer, as shown in **Table 2**. The majority of head and neck cancer were related to tobacco use.

**Table 2** Type of cancer seeking palliative care

Cancer	Male	Female	Total Number
Head and Neck Cancer	147(14.7%)	59(5.9%)	206(20.6%)
Ca Gall Bladder	69(6.9%)	93(9.3%)	162(16.2%)
Ca Oesophagus	83(8.3%)	49(4.9%)	132(13.2%)
Ca Lung	59(5.9%)	43(4.3%)	102(10.2%)
Ca Stomach	37(3.7%)	30(3.0%)	67(6.7%)
Ca Breast	4(4.9%)	97(95.0%)	101(10.1%)
Gynaecological malignancy	-	95(9.5%)	95(9.5%)
Colorectal cancer (CRC)	25(2.5%)	19(1.9%)	44(4.4%)
Others	48(4.8%)	45(4.5%)	93(9.3%)
Total	472(47.1%)	530(52.9%)	1002(100%)

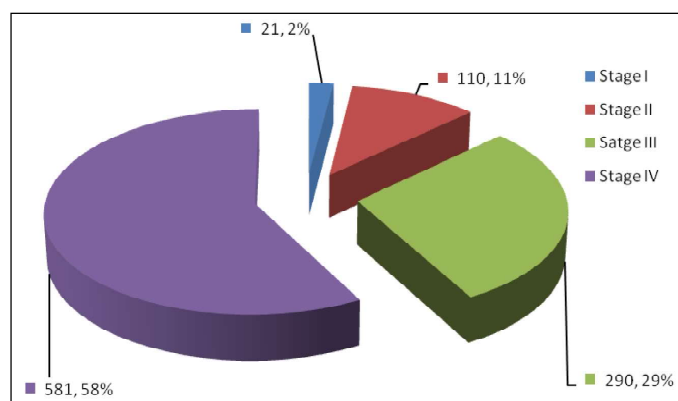
The six most common symptoms were pain (82.1%), anorexia (73.2%), generalized weakness (66.7), weight loss (56.6%), dysphasia (43.1%) and nausea and vomiting (40.1%), as shown in **Figure 1**. Patients having skeletal metastasis mainly reported pain as a disturbing symptom.



**Figure 1** Symptomatology of patients attending pain and palliative department

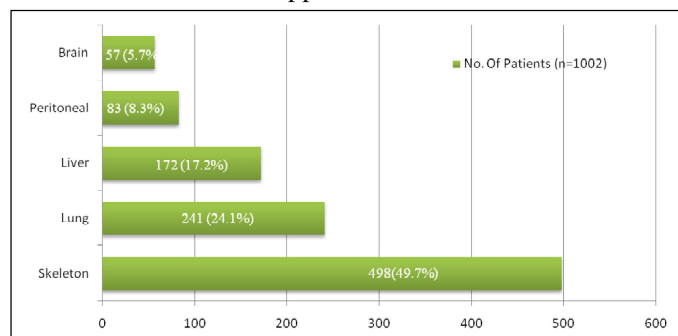
Referrals to the pain and palliative care were most common in stage IV patients, i.e., metastatic disease (58%), followed by patients with stage III, i.e., locally advanced disease (29%).

Patients with stage I or II disease accounted for only 13% of referrals. The condition is very early and usually has symptoms in a well manageable state (**Figure 2**).



**Figure 2** Stage-wise referral to pain and palliative care OPD

Skeleton (49.7%) was the most common site of metastasis in the patients, followed by lung (24.1%) and liver (17.2%) (**Figure 3**). The axial skeleton was the more common site of metastasis than the appendicular skeleton.



**Figure 3** Sites of metastasis

Out of the 1002 cancer cases, 823 (82.1%) patients reported pain as the most common symptom. Most of the cases (45.9%) were assessed with severe pain by NRS, followed by 32.2% with moderate pain (**Table 3**).

**Table 3** Assessment of pain among palliative care patients

Pain score	Numerical pain scale	Frequency (%)
Total cases with pain		823
Mild pain	1-3	180(21.9%)
Moderate Pain	4-7	265(32.2%)
Severe Pain	8-10	378(45.9%)

## DISCUSSION

Palliative care is an integral part of cancer care that needs to be provided throughout the care continuum, not just end-of-life care. Early integration of palliative care with standard oncologic care results in a clinically meaningful improvement in life quality. At the SCI, GMCH, we provide

comprehensive palliative care to patients with different cancer at different stages of their illness, thereby generating our data regarding palliative care in this part of the country.

Jivarajani PJ<sup>8</sup> et al., in their study, found that the maximum number of cases were in the 35-64 years of age group. The proportion of cancer cases was 62.59% and 71.20% in males and females, respectively, in this age group. There was an overall female preponderance in the age group 35-64 years, but the male majority was found in the age above 65. These findings were similar to the results of our study.

Jivarajani PJ<sup>8</sup> et al., in their study, found that the leading sites of cancer in males were mouth (14.56%) followed by the tongue (13.17%), lung (8.37%), oesophagus (6.26%), hypopharynx (4.22%), larynx (3.78%), tonsil (2.62%) and prostate (2.47%), i.e., head and neck cancer were most common in male. The leading sites among females were breast (24.85%) followed by the cervix (15.11%), ovary (5.38%), head and neck cancer, oesophageal cancer (3.45%) and lung (2.03%). These findings were similar to the results of the present study.

In the present study, we have found that pain was the most common symptom, followed by anorexia, dysphasia, weakness and sleeplessness. These findings were similar to a survey done by Naveh *et al.*, who reported that 66% of the patients had severe pain and Iyer *et al.* found that more than 90% of the patients expressed pain, weakness and anorexia.<sup>9,10</sup> Nilmana *et al.*, and Harding *et al.*, reported in their study that most of the cancer patients had pain (87.5%), weakness (77.7%).<sup>11,12</sup> Jivarajani PJ et al., in their research, also found that the majority of the patients studied had pain (77%), tiredness (96.5%), disturbed sleep (96.4%), weight loss (63.3%) and irritability (85.7%).<sup>8</sup>

**Limitation:** The present study included only the physical symptomatology of the patients, and the patient spontaneously reported the symptoms. However, social and psychological symptoms directly affect the quality of life of critically ill patients like those who have cancer and needs palliative care and consultation. A broader study for assessing those symptoms among patients may help the caregivers better manage the patients in providing better care.

## CONCLUSION

This study revealed that cancer patients experience many symptoms which affect their quality of life. The management of cancer pain is a critical issue in caring for patients with cancer. All professionals must ensure that patients receive an early and timely referral for palliative care at their disease's initial stage. A relatively large number of patients in our study presented to palliative care at an advanced

stage of disease when symptoms become severe, debilitating, multiple, and difficult to manage, indicating a lack of awareness of palliative care in medical professionals and the general population. More efforts need to be put into creating awareness, training in palliative care.

## Ethical Corrections

All data of the cases were treated with confidentiality, following the declaration of Helsinki.

## Acknowledgements

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## Disclosure

The authors report that there are no conflicts of interest in this work.

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## Authors' contributions

DS, DA, DH conceived the content, retrieved the data, wrote the manuscript, and approved the final version. DD, DS and SP extracted the data, wrote the paper, and approved the final version. SDG retrieved the data, wrote the manuscript, and approved the final version.

## Data Availability

The data used to support the findings of this study are included in the article.

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### RESEARCH PAPER

# A prospective study on spectrum of dermatoses of pregnancy in a tertiary care centre of Northern Assam

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**Background and aims:** During pregnancy, various metabolic, hormonal, and immunological changes occur and may also alter the course of pre-existing dermatological diseases and tumours. The present study aims to determine the prevalence of dermatoses of pregnancy and its various clinical spectrum in this region. **Methods:** A one-year cross-sectional study was conducted at a tertiary care hospital of Assam from July 2018 to June 2019. Pregnant women with cutaneous manifestations, irrespective of their gestational age, were included after full consent. A detailed history of obstetrics, medical and family history was taken from the selected patients. Clinical examinations and laboratory tests were performed. Data were documented on a predesigned proforma. The data were analysed using Microsoft- Excel. The data were presented as frequency and percentages. **Results:** Out of 5558 pregnant women, 150 (2.69%) women had dermatoses. Most of the patients were primigravida (52%) and at their third trimester (62%). The most common symptom was pruritus (52%) and Hyperpigmentation was the most common physiological cutaneous change (94.6%). Striae distensae was most observed over the abdomen (80%). Common sites of pigmentation were the external genitalia (93.3%) and breast (91.3%). Vascular changes were observed in 55 (36.6%) patients. Out of the 150 cases, 15 (10%) subjects had specific dermatoses of pregnancy, 89 (59.3%) cases had infection and 19 (12.6%) cases had non-infective dermatoses. **Conclusion:** Pregnant women are prone to suffer from a wide range of various dermatological problems. A conscientious and meticulous search into all cutaneous complaints of pregnancy will decrease the mortality and morbidity of pregnant women.

**Keywords:** Dermatoses; pregnancy; hyperpigmentation; physiological cutaneous change, striae distensae.

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### INTRODUCTION

Dermatoses during pregnancy are common and in some cases, cause anxiety in the perspective mother. During pregnancy, various metabolic, hormonal and immunological changes occur.<sup>1</sup> These alterations may range from normal physiological skin changes in almost all pregnancies to

pathological, recurrent and specific to pregnancy. Pregnancy may also alter the course of pre-existing dermatological diseases and tumours.<sup>2</sup>

Dermatoses during pregnancy are exceedingly common. Although the physiological skin changes during pregnancy are usually not harmful to the health of the mother or fetus,

some can be significant and of importance cosmetically and dermatologically.<sup>3</sup> During gestation, immunological, endocrinal and vascular changes make pregnant women susceptible to aggravation and modification of specific cutaneous dermatoses. Pregnancy-specific skin dermatoses, including the Prurigo of pregnancy, polymorphic eruption of pregnancy, pemphigoid gestationis, and intrahepatic cholestasis of pregnancy, are due to an ill-defined heterogeneous group of pruritic skin eruptions.<sup>4</sup> The specific dermatoses of pregnancy, which bear a poor prognosis are fortunately rare.

The dermatoses of pregnancy may range from physiological skin changes in pregnancy, dermatoses and cutaneous tumors affected by pregnancy, to specific dermatoses of pregnancy.<sup>5</sup> The cutaneous changes cause concern to the young expectant mothers. The concerns may be due to cosmetic appearance and the chance of recurrence during a subsequent pregnancy and its effect on the fetus in terms of morbidity and mortality.<sup>6</sup>

Awareness and recognition of these conditions and familiarity with their outcomes and treatment are essential for a better management and care of pregnant women. So the objective of our study was to determine the prevalence of dermatoses of pregnancy and its various clinical spectrum in this part of Assam.

## MATERIALS AND METHODS

This is a Prospective Study which was conducted in the Outpatient Department (OPD) of Dermatology in collaboration with Antenatal OPD in a tertiary care hospital of Assam from July 2018 to June 2019. Clearance from the Ethical Committee and written informed consent was taken from all patients. The study material comprised of serially enrolled pregnant women attending the outpatient department with cutaneous manifestations, irrespective of their gestational age. Those patients who did not give consent were excluded from the study. A detailed history of obstetrics, medical and family history was taken from the selected patients. Chief complaints, duration of illness, the onset of disease, evolution of the disease, secondary changes, associated infection and specific enquiry for past or family history of dermatoses related to pregnancy were recorded. The morphology and distribution of the lesions were accurately documented. All patients were subjected to thorough clinical examination. The skin lesions (e.g., macule, papule, vesicle, bulla, pustule, plaque, nodule, wheal, telangiectasia, target lesion, purpura, striae, erythema, hyperpigmentation), hair changes, nail changes (e.g., transverse grooving, brittleness, distal onycholysis etc.), oral and genital mucosal changes were recorded. In all cases, routine blood, stool & urine examination, ABO-Rh grouping,

blood sugar estimation and VDRL were carried out. Special investigations were done on individual merit. The detailed history and findings of the patients were recorded in a predesigned Proforma. The data were analyzed using Microsoft- Excel. The data were presented as frequency and percentages.

## RESULTS

A total of 5558 pregnant women were screened attending the Dermatology OPD and Antenatal OPD in the study, out of which 150 (2.69%) women had dermatoses.

**Table 1** Socio-demographic and symptom profile of the participants

Variables	Frequency	Percentage (%)
<b>Age</b>		
16-25	96	64
26-35	51	34
>36	3	2
<b>Gravida</b>		
Primigravida	78	52
Multigravida	72	48
<b>Trimester</b>		
1 <sup>st</sup>	15	10
2 <sup>nd</sup>	42	28
3 <sup>rd</sup>	93	62
<b>Presenting Symptom</b>		
Pruritus	78	52
Vaginal discharge	30	20

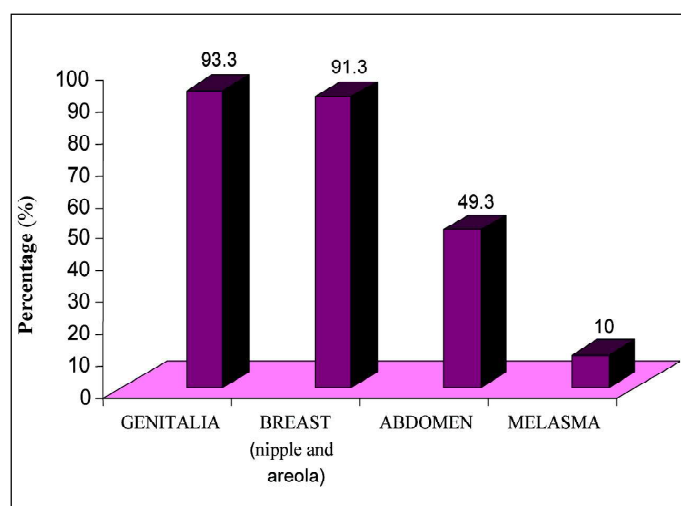
Majority (64%) of the patients belonged to the age group of 16 to 25 years. A slight preponderance was seen in primigravida (52%). Most of the patients were in their third trimester (62%). The most typical presenting symptom was pruritus (52%) followed by vaginal discharge (20%), as shown in **Table1**.

**Table 2** Physiological cutaneous changes among study participants

Physiological change	Gravida		Total No. of Patients	Percentage (Out of 150)
	PRIMI	MULTI		
Hyperpigmentation	70	72	142	94.6
Striae distensae	57	72	129	86.0
Vascular changes	17	23	40	26.7
Nail changes	6	3	9	6.0

Hyperpigmentation was the most common physiological cutaneous change seen in 142 (94.6%) cases, followed by striae distensae and vascular changes (**Table 2**).





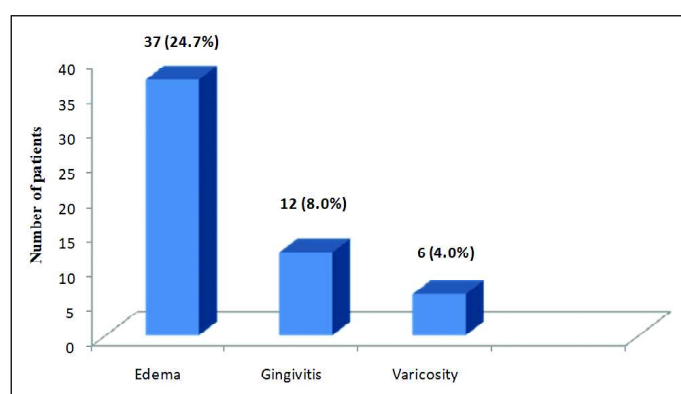
**Figure 1** Distribution of Hyperpigmentation

The most common site of pigmentation during pregnancy was the external genitalia, as seen in 140 (93.3%) cases. In 137 (91.3%) cases, breast pigmentation was observed in the abdomen in 74 (49.3%) patients. In addition, melasma was observed in 15 (10%) cases (**Figure 1**).

**Table 3** Distribution of striae distensae

Site of striae	Number of patients	Percentage(%) (Out of 150)
Abdomen	120	80
Thighs	32	21.3
Hips & buttocks	7	4.7
Breast	5	3.3

Striae distensae was most observed over the abdomen (80%) and thighs (21.3%) among cases, as shown in **Table 3**.



**Figure 2** Distribution of Vascular changes among study participants

Vascular changes were observed in 55 (36.6%) patients. Out of these, oedema of legs was observed in 37 (24.7%) patients, gingivitis in 12 (8%) patients and varicosity of veins of lower limbs in 6 (4%) patients (**Figure 2**).

**Table 4** Distribution of different dermatoses among study participants

Dermatoses type	Number of patients	Percentage (%)
<b>Specific dermatoses of pregnancy</b>	<b>15</b>	<b>10</b>
Prurigo of pregnancy	12	8.0
Pruritus gravidarum	2	1.3
Pemphigoid gestationis	1	0.7
<b>Infective dermatoses</b>	<b>89</b>	<b>59.3</b>
Vaginal candidiasis	30	20.0
Scabies	24	16.0
Dermatophytosis	21	14.0
Condyloma acuminata	5	3.3
Herpes zoster	3	2.0
Herpes simplex	3	2.0
Syphilis	2	1.3
Leprosy	1	0.7
<b>Non-infective dermatoses</b>	<b>19</b>	<b>12.6</b>
Acne vulgaris	14	9.3
Urticaria	2	1.3
Vitiligo	2	1.3
SLE	1	0.7

Out of 150 patients, 15 (10%) cases had specific dermatoses of pregnancy. Prurigo of pregnancy was the most common particular dermatoses observed in 12 (8%) cases. Out of 150 pregnant women, 89 (59.3%) patients had infection among which vaginal candidiasis was the most common infection seen in 30 (20%) cases, followed by scabies in 24 (16%) cases and dermatophytosis 21 (14%) cases. A minor portion of the patients had other infections like condyloma acuminata, herpes zoster, herpes simplex, syphilis and leprosy.

Acne vulgaris was the most common non-infective dermatoses and was observed in 14 (9.3%). Other dermatoses seen are urticaria and vitiligo in 2 (1.3%) cases each and SLE in 1 (0.7%) case, as shown in **Table 4**.

## DISCUSSION

In the present study, out of 5,558 pregnant women attending the Dermatology OPD and the Antenatal OPD of a tertiary care centre from July 2018 to July 2019, 150 cases presented with various cutaneous manifestations with an overall prevalence of dermatoses in pregnancy of 2.69%. Multiple studies from India reported prevalence rates of dermatoses during pregnancy ranging from 0.59% to 9.67%.<sup>7,8</sup>

The majority of the cases of dermatoses of pregnancy belonged to the age group of 16-25 years (64%) followed by 26-35 years (34%) cases and only 2% cases were in the age group of more than 35 years in the present study. Higher occurrence of dermatoses of pregnancy among women in the age group 18-35 years are reported from

similar other studies.<sup>7,9,10</sup> In contrast to another study reporting majority of their patients in 11-20 years age group<sup>8</sup>, the higher prevalence in 16-25 years age group in our study is because, in our society, girls are married in a relatively higher age group.

In our study, primigravida accounted for 78 (52%) cases and multigravida 72 (48%) cases. Similar observations were reported in some previous research outcomes.<sup>8,11-13</sup> As the primigravidas are more apprehensive and conscious; they may report for medical care more frequently than the more experienced multigravidas. However, the findings contradict some other studies where most of the patients were reported to be multigravidas.<sup>9,10,14</sup> Most of the patients (62%) in the present study were in their third trimester. Various studies reported a similar trend.<sup>8-13</sup> As the cutaneous changes frequently occur in late pregnancy; the reporting occurs less during the first and second trimesters.

Pruritus (52%) and vaginal discharge (20%) was the most common presenting symptom observed among the study participants. Scabies was found as the cause of pruritus, which accounted for overall about 16% and among specific dermatoses of pregnancy 10% cases. Another study also reported similar findings.<sup>8</sup> Vaginal discharge was seen in 30 patients, all of which had vaginal candidiasis.

In the current study, hyperpigmentation (94.6%) was the most observed physiological cutaneous change among both multigravida (100%) and primigravida (89.7%) women. Hyperpigmentation in the present study was primarily observed over external genitalia (93.3%), nipple and areola (91.3%) and abdomen (49.3%). Various studies from different parts of India<sup>7-14</sup> and western literature<sup>5,17</sup> reported similar findings. Melasma was found in 15 (10%) cases comparable to some studies undertaken in India.<sup>7,8,10</sup> However, in contrast to our results, several researchers reported melasma in about 35% to 65% of Indian pregnant women.<sup>9,12-14</sup> Pieces of literature from western countries reported melasma in upto 70% of fair-skinned pregnant women.<sup>2,15</sup> The higher prevalence of melasma reported in western countries may be because mild pigmentary changes are more visible in the fair skin.

Striae distensae were found in 120 (80%) cases of pregnant women with 100% involvement in multigravidas. The most common site was abdomen 80%, followed by thighs in 21.3%, hips & buttocks in 4.7% and breast 3.3%. The observations were concordant with studies from different parts of India.<sup>7,13</sup> Another study from Kashmir reported striae distensae in only 38.7% of cases. The incidence of striae distensae of up to 90% was reported in studies conducted among western pregnant women.<sup>6,17</sup>

Vascular changes were observed in 36.6% of the cases. Varicosity of the lower limb, specifically in the latter part of pregnancies, was observed in 6 (4%) cases. Findings similar to this were reported in a study.<sup>7</sup> Similar to our

results of 8% cases with gingivitis, another study reported 10% of marginal gingivitis.<sup>8</sup>

Out of 150 pregnant women, 15 (10%) cases had specific dermatoses of pregnancy, among which prurigo of pregnancy was the most common specific pregnancy dermatoses accounting for 12 (8%) cases (**Figure 3**). Studies in the Indian context reported pregnancy-specific dermatoses as low as 2% to as high as 38.3%.<sup>1,7-14,18</sup> Pruritus gravidarum was observed in 2 (1.3%) cases, out of which one was primigravida and the other was multigravida with a history of itching in previous pregnancies. Pruritus started between 28-32 weeks of pregnancy without skin lesion. In both cases liver function test was found to be altered. A study reported Pruritus gravidarum in Indian women as 1.1%.<sup>16</sup> In our study, only 1 (0.67%) case of Pemphigoid Gestationis was found. The patient was a multigravida in her second trimester. Low percentage of Pemphigoid Gestationis was reported in some other studies.<sup>15,18</sup>



**Figure 3** Prurigo of Pregnancy

Infective dermatoses were the most reported type of dermatoses (59.3%) among the study participants. The finding agrees with a report.<sup>10</sup> Vaginal candidiasis was observed in 30 (20%) cases. The results are in agreement with some other research outcomes.<sup>7,8</sup> Among the infectious dermatoses cases, 16% were observed with scabies with positive family history in the majority of the patients.



**Figure 4** Herpes Zoster Ophthalmicus

Syphilis was encountered in 2 (1.3%) cases. Both cases were in their secondary stages. A few studies that reported a low percentage of syphilis among Indian pregnant women support the present finding.<sup>7,8</sup> Similarly, condyloma accuminata was observed in 5 (3.3%) cases. The above observations were almost like the findings of another study.<sup>8</sup> In the present study, 3 (2%) cases of herpes zoster appeared for the first time and showed extensive involvement (**Figure 4**). Another 3 (2%) cases of herpes simplex labialis appeared first and showed dissemination to other sites. In the present study, dermatophytosis was seen in 21 (14%) patients. Raj et al., 1992 reported 16 (14.03%) cases of dermatophytosis, which coincides with the findings of our study.<sup>7</sup> Leprosy was observed in 1 (0.7%) multigravida case during her first trimester. Histopathological examination was consistent with tuberculoid leprosy.

Among the study participants, 12.6% were observed with non-infective dermatoses. Other studies from India reported non-infective dermatoses during pregnancy as 4% to 11%.<sup>9,10,14</sup> In our study, acne vulgaris was observed in 14 (9.3%) cases. Also, vitiligo and urticaria were found in 2 (1.3%) patients each. The findings agree with a study.<sup>7</sup> Systemic lupus erythematosus (SLE) was found in 1 (0.7%) case with a past SLE history (**Figure 5**). Severe exacerbation was observed as SLE during pregnancy may precipitate or flare up during pregnancy.<sup>15</sup>



**Figure 5** Systemic lupus erythematosus

## CONCLUSION

The pregnant woman is prone to suffer from various dermatological problems, including sexually transmitted diseases, apart from the specific dermatoses of pregnancy. Specific dermatoses of pregnancy can sometimes result in severe foetal outcomes. This study emphasizes the need for a conscientious and meticulous search into all cutaneous pregnancy complaints rather than attributing them to an inevitable physiological process that may enable creating a conducive environment for a better and healthier life for the mother and yet to be born baby.

**Limitations:** Limitation of this study include small sample size and single centre design.

**Strength of the study:** This study has been conducted in the Northern part of Assam and no such study was conducted earlier in this part.

**Recommendation:** This type of study should be conducted in Regional level.

**Conflict of interest:** None declared.

**Source of funding:** None.

**Authors' contributions:** All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the report has been submitted and agree to be accountable for all aspects of the work.

**Ethical corrections:** All data of the cases were treated with confidentiality, following the declaration of Helsinki. Ethical approval was obtained.

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### RESEARCH PAPER

# The ethnic background of the prevalence of different rheumatological diseases in a tertiary care hospital of North-East India -a hospital-based observational study

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**Background and aims:** The prevalence of rheumatological diseases varies among different populations across the globe. Moreover, different ethnic groups in the same population or geographical regions also show diversity in rheumatological disease epidemiology. We realised that there are not many studies about this beneficial correlation in the North-Eastern part of India. Hence, we decided to report the same. **Material and Methods:** A total of 800 patients of >12 years of age, irrespective of gender, attended the Rheumatology outpatient department (OPD) of Gauhati Medical College and Hospital (GMCH), Assam, India and fulfilled the standard diagnostic criteria for rheumatological diseases were included in the study. **Results:** Out of 800 patients in our study, 52.5% had Rheumatoid Arthritis (RA), 12% had Spondyloarthropathy (SpA), and 9% had Systemic Lupus Erythematosus (SLE). Other reported disorders were Mixed Connective Tissue Disease (MCTD) (8.6%), Sjogren's Syndrome (5.3%), gout (5.2%), fibromyalgia (3.8%) and Systemic sclerosis (3.6%). Among the ethnic groups, RA was most prevalent among Kayastha (29.1%), followed by Bengali Muslim (22.1%), Brahmin (11.7%), Manipuri Meitei (8.3%), Boro (4.8%). SLE was more prevalent in the ethnic group Kaibarta (30.6%), followed by Kayastha (22.2%) and Ahom (8.3%). At the same time, SpA was commonly seen among the Kayasthas (33.3%), followed by the Bengali Muslims (29.2%), Brahmins (7.3%) and Manipuri Meitei (4.2%). **Conclusion:** There is a high prevalence of different rheumatological diseases among the people inhabiting the North-Eastern part of India. Different ethnic groups have a varied predisposition to the conditions. Further research is warranted to establish the concept of regional ethnic diversity and disease epidemiology.

**Keywords:** Rheumatological diseases; Ethnicity; North-East India.

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### INTRODUCTION

Depictions of ethnicity may vary by context as distinct meanings are usually assigned about different clinical practice objectives, medical and social science research, national surveillance of health statistics and even census by census.<sup>1</sup>

The risks of developing different ailments vary according to cultural and ethnic origin. It is commonly known that patients from different ethnic backgrounds have varied beliefs

about disease, its causality or management, which are primarily affected by cultural or communication obstacles.<sup>2-4</sup> Inhabitant groups of specific regions with differences governed by culture, creed or ethnicity also illustrate differences in their illness behaviour.

Identifying and analysing ethnic variation in disease epidemiology can generate signals towards environmental or genetic factors that affect disease risk. If an ethnic

difference in disease risk has an environmental justification, this difference is supposed to ‘wear off’ within a few generations after migration.<sup>5</sup> If, on the other hand, genetic factors underlie an ethnic difference in disease risk, we would expect this ethnic difference to persist in populations where migrants have been settled overseas for many generations and to be observed consistently in all countries where a different migrant group has settled.

Ethnic factors such as beliefs and cultural context, comprehended by language and social factors, affect access to and outcome of healthcare related to chronic diseases. Due to globalisation, the ethnic distribution of a nation is vastly influenced by the movement of ideologies across the traditional natural border, pattern of migration and political debate. To confront these challenges restructuring of healthcare delivery system is a prerequisite.<sup>6</sup>

Where there has been a mixture between ethnic groups that differ in risk for disease, studies of how the risk for illness varies among them can help distinguish between genetic and environmental explanations for the difference in disease risk and help define the specific genetic model.<sup>5</sup>

Northeast India comprises eight states with different ethnic groups who came from different directions at other historical times. The tribes of Northeast India may be considered specific examples of variation and diversity of biosocial and cultural life in terms of susceptibility to different diseases, including rheumatological disorders.

No adequate studies have yet been undertaken on the risk for various rheumatological disorders like SLE, RA, etc., to admixture in populations of northeast India. The present study is one of its kind in this direction, which was objectivist to identify such ethnic propensity or variability towards rheumatological disorders in this specific Indian geography.

## MATERIAL AND METHODS

The study was conducted among the patients attending the Rheumatology OPD of GMCH, Assam, India, within one year from August 1<sup>st</sup> 2018, to July 31<sup>st</sup> 2019.

**Inclusion criteria:** All patients attending the Rheumatology OPD of our unit were included irrespective of age and sex.

**Exclusion criteria:** Patients having a non-rheumatological diagnosis or incomplete data were excluded from the study.

**Diagnosis:** Clinical diagnosis and differentials were reached from comprehensive history and physical examination supplemented by appropriate and relevant laboratory investigations, as shown in **Table 1**. Appropriate laboratory investigations were utilised to confirm the diagnosis, assess disease severity, and modify treatment in line with the specific requirement during the initial and follow up visits.

**Table 1** List of investigations

Sl.No.	Investigations
1	Complete blood count
2	Blood urea, serum creatinine, random blood sugar, liver function tests
3	Serum uric acid level
4	Thyroid profile
5	Rheumatoid factor
6	Anti-CCP antibody
7	HLA-B27 typing
8	Radiological investigations (X rays of joints including the knee, lumbosacral spine, X-rays of hands and feet, chest Xray)
9	MRI
10	Coomb's test
11	ANCA
12	Investigations 1-4 were done routinely in all patients; the rest were planned according to the presentation of patients
13	ANA assay including various specific antibodies

Distinct updated diagnostic criteria were used for the diagnosis of different rheumatological disorders. Like ACR/EULAR<sup>6</sup> Criteria for Rheumatoid Arthritis,<sup>7</sup> Modified New York Criteria (1984) for Ankylosing Spondylitis,<sup>8</sup> Revised American Rheumatism Association Criteria for Systemic Lupus Erythematosus (SLE)<sup>9</sup> and Kahn Criteria for Mixed Connective Tissue Disease (MCTD) were used to reach the confirmatory diagnosis.

**Statistical analysis:** Appropriate descriptive statistical methods were utilised to describe the analysis of this simple observational study.

**Ethical consideration:** Ethical approval was taken from the ethics committee of Gauhati Medical College and Hospital.

The broader reference list of ethnic communities inhabiting the Northeast part of India is shown in **Table 2**.<sup>10-14</sup>

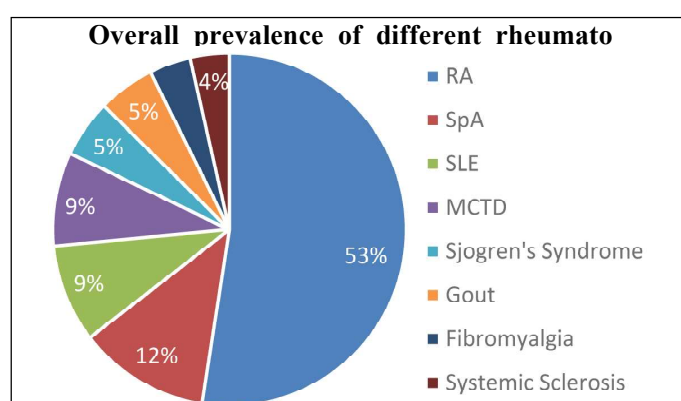
**Table 2** Ethnic communities in Northeast India

Name of State	Ethnic communities
Assam	<b>Assamese people:</b> Ahoms, Assamese, Brahmins, Assamese Kayastha, Bodo, Rabha, Tiwa, Karbi, Dimasa, Mising, Rajbongshi, Deori, Garo, Khasi, Santal, Chutiya, Bodo-Kachari, Tea tribes of Assam, Bengali, Muslims, Tai phake people, Tibeto-Burman, Jalia kaibarta, Khamyang people, Sutradhars of Assam Nath.

<b>Arunachal Pradesh</b>	Monpa, Adi, Nyishi, Tangsa, Mishmi, Hill, Miri, Chakma, Tagin, Hrusho, Padam, Minyong, Jingpo, Bugun, Galo, Lisu, Chugpa, Membra, Miju, Mishmi, Tai phake, Deori, Tani, Tutsa, Na
<b>Manipur</b>	Meitei, Tangkhul, Gangte, Pangal, Liangmai, Vaiphei, Poumai, Rongmai, Maring Naga, Maram Naga, Monsang Naga, Manipuri Brahmin, Mao Naga, Kom people, Anal Naga, Sukta people, Bishnupuria Manipuri people, Manipuri Kshatriyas
<b>Meghalaya</b>	Khasi, GaroJ, aintia, Bengali, Nepali, Hajong, Biate, Koch, Tiwa, Rabha, Kuki, Sheikh
<b>Mizoram</b>	Lusei people, Pawi, Paite, Mara, Ralte, Hmar
<b>Nagaland</b>	Angami Naga, Lotha Naga, Ao Naga, Rengma Naga, Chakhesang Naga, Phom Naga, Pochury Naga, Khaimniung Naga
<b>Tripura</b>	Bengalis, Tripuri people include- • Debbarma • Tripura • Reang • Jamatia • Kolo • Noatia • Murasing • Uchoi • Rupini; Chakma people, Halem tribe, Panoriya

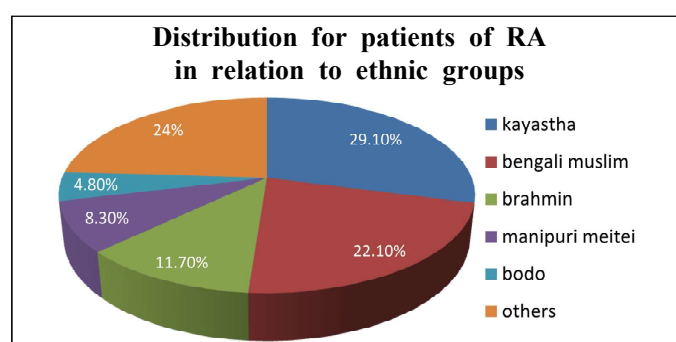
## RESULTS

Out of 800 patients in our study, 52.5% (420/800) had RA, 12% (96/800) had SpA, 9% (72/800) had SLE. Other rheumatological disorders were MCTD (8.6%), Sjogren's Syndrome (5.3%), gout (5.2%), fibromyalgia (3.8%) and Systemic sclerosis (3.6%), as shown in **Figure 1**.



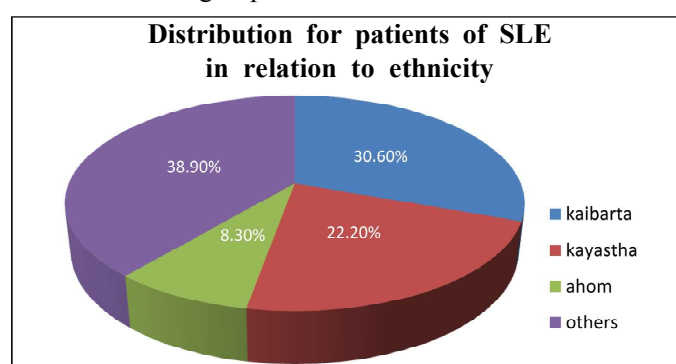
**Figure 1** Overall prevalence of different rheumatological diseases

If we see the ethnic distribution for rheumatoid arthritis (RA), the most common rheumatological illness in this study, it was found most prevalent among Kayastha (29.1%), followed by Bengali Muslim (22.1%), Brahmin (11.7%), Manipuri Meitei (8.3%) and Boro (4.8%).



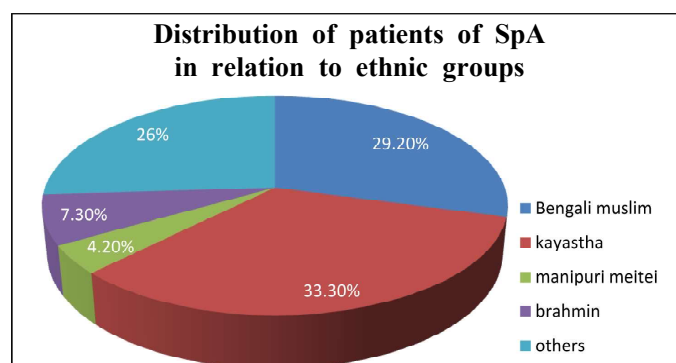
**Figure 2** Distribution for patients of RA about different ethnic groups

SLE was most prevalent in the ethnic group Kaibarta (30.6%), followed by Kayastha (22.2%) and Ahom (8.3%). Others include- Sutradhar (2.8%), Garo (2.8%), Chutia (2.8%), Nepali (2.8%), Bengali Muslim (5.6%), tea tribe (2.8%), Naga latha (2.8%), Keot (5.6%), Manipuri Meitei (5.6%), Rajbongshi (5.6%). The distribution of SLE in the different ethnic groups is shown in **Table 3**.



**Figure 3** Distribution for patients of SLE about ethnicity

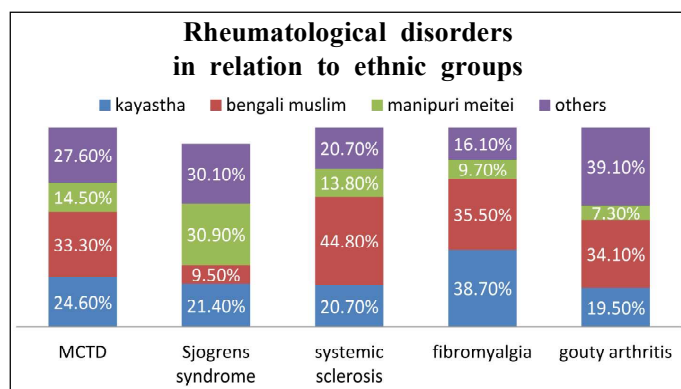
The spA was most prevalent among the Kayasthas (33.3%), followed by the Bengali Muslims (29.2%), Brahmins (7.3%) then by group Manipuri Meitei (4.2%). Other groups reporting with SpA were Kaibarta (2.1%), Khasi (1.04%), Garo (1.04%), Karbi (1.04%), Nath (3.1%), Koch (3.1%), Hira (1.04%), Sutradhar (2.1%), Rajbongshi (3.1%), Jain (2.1%), Bodo (3.1%), Tea tribe (3.1%) and Keot (2.1%).



**Figure 4** Distribution of patients of SpA with ethnic groups

In our study, we found that MCTD was most prevalent among the Bengali Muslims (33.3%), followed by Kayasthas (24.6%) and Manipuri Meitei (14.5%). Sjogren's Syndrome was most prevalent among the patients from the Manipuri Meitei community (30.9%), followed by Kayasthas (21.4%) and Bengali Muslims (9.5%). Systemic sclerosis had the highest prevalence among Bengali Muslims (44.8%), followed by Kayasthas (20.7%) and Manipuri Meitei (13.8%). Fibromyalgia was found to be most prevalent among the Kayasthas (38.7%), followed by Bengali Muslims (35.5%) and Manipuri Meitei (9.7%). Gouty arthritis was most prevalent among patients from the Bengali Muslim community (34.1%), followed by Kayasthas (19.5%) and Manipuri Meitei (7.3%).

Others like Ahom (2.8%), Chutia (0.4%), Keot (0.2%), Khasi (0.2%), Teatribe (0.7%), Nath (1.2%), Naga (1.7%), Nepali (1.4%), Kaibarta (3.6%), Rajbongshi (3.3%), Rabha (1.7%), Kumar (1.2%), Koch (1.4%), Khasi (2.1%) and Deori (0.7%).



**Figure 5** Prevalence of rheumatological disorders in different ethnic groups

Looking at Figure 5, we can infer that MCTD was most prevalent among the Bengali Muslims (33.3%), followed by Kayasthas (24.6%) and Manipuri Meitei (14.5%). Sjogren's Syndrome was most prevalent among the patients from the Manipuri Meitei community (30.9%), followed by Kayasthas (21.4%) and Bengali Muslims (9.5%). Systemic sclerosis had the highest prevalence among Bengali Muslims (44.8%), followed by Kayasthas (20.7%) and Manipuri Meitei (13.8%). Fibromyalgia was found to be most prevalent among the Kayasthas (38.7%), followed by Bengali Muslims (35.5%) and Manipuri Meitei (9.7%). Gouty arthritis was more prevalent among the Bengali Muslim community (34.1%), followed by Kayasthas (19.5%) and Manipuri Meitei (7.3%).

## DISCUSSION

Rheumatological diseases like RA, SpA, SLE are quite prevalent in India, and their prevalence varies in different racial groups and geographical areas. To the best of our knowledge, this study is one of the first studies that describe various rheumatic diseases reported in the tertiary health

care facility in Assam and mapped their prevalence against various ethnic groups. There are overall 106 ethnic groups that live in this region, covering 262179 km<sup>2</sup> of geographical area. Out of these, 17 different ethnic groups reported rheumatic disorders at our centre, whose data was captured in our study. We observed wide variation in the prevalence of these diseases among various ethnic groups.

Rheumatoid arthritis was most prevalent among the rheumatological diseases, followed by Spondyloarthropathy and Systemic Lupus Erythematosus in our study. Another study based on COPCORD (community-oriented program for control of rheumatic diseases) published in 2015 also reported a high burden of RA in India with a point prevalence of 0.7%.<sup>15</sup> RA is also the most studied disease among rheumatological conditions written by Misra DP et al.<sup>16</sup> The reported prevalence of RA in India is almost like that among developed countries. However, it is higher than the disease load in China, Indonesia, the Philippines, and rural Africa. This data is in line with the fact that the population from north India is genetically closer to Caucasians than other ethnic groups.<sup>17</sup>

Rheumatological diseases were more commonly reported in some ethnic groups like Kayastha, Bengali Muslim, Kaibarta, Bengali Muslim and Manipuri Meitei. RA was more widely seen among Kayastha, Bengali Muslim and Brahmin ethnicities. At the same time, SpA was more frequent among Kayastha, Bengali Muslims and Manipuri Meitei.

As per our data, Kaibarta ethnic group reported the highest prevalence of SLE. Other groups in which SLE was prevalent included Kayastha and Ahom. We could not find any published literature reporting the prevalence pattern of SLE based on ethnicity among the population of North-East India. Though a few researchers previously discussed the ethnic distribution of SLE, reporting 2.5 times higher incidence and prevalence reported in South Asian ethnic groups than white Caucasians irrespective of their country of birth.<sup>18</sup> Even the disease expression is also observed to be different in different ethnic groups. Clinical indications like renal involvement, disease severity, photosensitivity etc., show variations in various ethnicities.

Looking at the currently available data, both increased prevalence and diverse disease manifestation have some solid genetic basis. However, this area needs a lot more meticulous research to arrive at a factual conclusion.

## CONCLUSION

The data from our study leads to the conclusion that there is a high prevalence of different rheumatological diseases among the people inhabiting the North-Eastern part of India, with different ethnic groups having a varied predisposition to the conditions. Like in the rest of India, Rheumatoid



Arthritis is also the most prevalent rheumatological disorder in North-East India. We strongly feel that this study will be an eye-opener for researchers further to investigate disease prevalence and variation among various ethnicities.

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### RESEARCH PAPER

# Awareness among registered medical practitioners on legal aspects of workplace violence: a questionnaire-based study

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**Background and aims:** In recent years, violence against medical practitioners at workplaces has increased in India. Good knowledge and awareness on preventing and handling workplace violence at hospitals can help us mitigate such incidents. The study aimed to gauge the level of understanding and knowledge among medical practitioners on the legal aspects of violence against the medical profession. **Method:** This cross-sectional study was conducted among 451 randomly selected medical practitioners. The data was collected using a pretested Google form questionnaire after obtaining consent. The collected data was analysed by using Microsoft and SPSS software Version 24.0. **Results:** Out of 451 medical practitioners, 429(95%) were concerned about the prevailing violence against medical practitioners, 112(25%) were aware of the Medicare Service persons & Medicare services institutions Act. 198(44%) were aware of the various Indian Penal Codes (IPC) related to Hurt, Injury, and Assault, and 133(30%) were aware of the IPCs related to Defamation and Outraging the Modesty of a Woman. 75% of the participants showed hesitance in taking legal action due to inadequate knowledge of our Legal system. **Conclusion:** Most medical practitioners did not know the legal perspectives in handling violent outbreaks. A good medico-legal education needs to be included in the curriculum, which will help break the inhibitions to approach the Police and the Court of Law. A solid representation to implement or amend the existing legal system to protect the medical fraternity is required.

**Keywords:** Violence against medical professionals; Legal awareness; Acts; Indian Penal Codes.

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## INTRODUCTION

New emotions like anarchy, aggression, and mob mentality are creeping in as violence against medical professionals in recent years. Such violence has existed from the pre-biblical era since the dawn of medicine.<sup>1</sup> History says doctors were

penalised for not being effective in Egypt, Greece, and Ancient India.<sup>2</sup>

Violence is an act of aggression that may range from a stare, verbal abuse, threats, intimidation, harassment, physical attacks, or damage to body, mind, reputation, or property.

The World health organisation (WHO) says that healthcare providers face the highest risk of violence at the workplace in their Global campaign for violence prevention.<sup>3</sup> In India, doctors are being subjected to an unchecked rise in violent outbreaks during work.<sup>4,5</sup> As per the Indian Medical Association (IMA) reports, about 75% of medical practitioners experience violence at the workplace.<sup>6</sup> Literature also suggests that innumerable cases go unreported or called off after compromise. Very few go to the court of law, and the offenders are hardly penalised.<sup>7</sup> The principal causes of such violent outbreaks at hospitals are poor communication, dissatisfaction of the patients, cost of health care, the intentional mob mentality of the people, vulnerable work environment and lack of judicial support.<sup>7,8</sup>

In Tamil Nadu, the Legislative assembly has published The Act 48 - The Tamil Nadu Medical care service persons and Medicare services institutions (Prevention of Violence and Damage or loss to property) Act 2008. This act declares that any violence at the hospital shall be considered cognisable and non-bailable. Many other legal provisions in our legislation offer legal protection to the victims of violence. We can attribute several causes to violence at healthcare establishments. This study aims to unveil the knowledge and understanding of the various medico-legal aspects concerning workplace violence among doctors.

## MATERIALS AND METHODS

This cross-sectional study was conducted among randomly selected 451 registered medical practitioners across all specialties in Tamil Nadu. Institutional Human Ethics Committee clearance was obtained before the commencement of the study. A questionnaire with a disclaimer on confidentiality was sent to the participants across Tamil Nadu as a Google form. An informed consent form was attached, along with the pretested questionnaire. The data obtained from Google forms were uploaded to Microsoft excel sheets and analysed using the SPSS version-24. The sample size required was estimated as 451 after adjusting 20% non-responders using the formula  $n = 4pq/d^2$  where prevalence  $p = 38$ ,  $q = 62$  and considering absolute precision  $d$  as 5% (Calculated from the prevalence of violence among doctors as 38% reported by Kesavan R et al.<sup>9</sup>).

## RESULTS

A total of 451 practitioners participated in our study. Most of the participants (64%) were men, and 78% specialised. Almost 68.5% of the participants worked in the private sector or operated their clinical establishments. Concerning the work experience, our study group had nearly an equal distribution of participants having a work experience of fewer than ten years and more than ten years (Table 1).

**Table1** Demographic pattern of the study Population (n=451)

Subject	Characteristics	Frequency (%)
Gender	Males	290 (64%)
	Females	161 (36%)
Qualification	Only MBBS	99 (22%)
	Specialisation	352(78%)
Subspecialty	Medical and allied fields	173 (38%)
	Surgical and allied fields	206 (46%)
	Obstetrics and Gynecology	33 (7%)
	Diagnostics	25 (5.5%)
	Administrators	14 (3%)
Nature of the workplace	Government	142 (31.5%)
	Non Government	309 (68.5%)
Locality	Urban	317 (70%)
	Rural	134 (30%)
Work experience	Less than 10 Years	201 (45%)
	More than 10 Years	250 (55%)

As seen from Table 2, most study participants knew what constitutes violence against a medical practitioner and what an act of violence means.

**Table 2** Knowledge among medical practitioners on what constitutes violence against them

Sl. No	Type of violence	Frequency (%)
1	Intimidating Gestures	348 (77.2%)
2	Verbal threats	408 (90.5%)
3	Physical threats	423 (94%)
4	Damage to Mind, Body, and Property	437 (97%)

Most participants of this study knew the possible reasons behind the outbreaks of violence against medical professionals. The majority (87%) claimed that misguided conclusions from the internet and other sources influence such incidents. An unforeseen outcome of the treatment (84%) was the second most agreed reason behind the violent outbreaks. Other reasons were financial issues, lack of proper care, and lack of knowledge on the liabilities of the offenders (Table 3).

**Table 3** Knowledge among medical practitioners on reasons for violent outbreaks

Sl. No	Violent outbreaks in a clinical establishment - Primary reasons:	Frequency (%)
1	Misguided conclusions from the internet and other sources.	393 (87%)
2	An unforeseen outcome of the treatment.	377 (84%)
3	Financial issues.	329 (73%)
4	Lack of proper care and other services	302 (67%)
5	Lack of knowledge and liabilities of the patients and their relatives.	280 (62%)

Regarding the prevention strategies to handle violent outbreaks, more than 80% of the participants in our study opined that maintaining good rapport, displaying legal liabilities, installing CCTV cameras, and efficient coordination with other staff were the best ways to prevent violent outbreaks (**Table 4**).

**Table 4** Knowledge among medical practitioners on prevention and practice in handling violent outbreaks

Sl. No	Prevention of violence in a clinical establishment- Strategies.	Frequency (%)
1	Maintaining good rapport with the patients and their relatives.	396 (88%)
2	Display legal liabilities to the offenders.	388 (86%)
3	Install CCTV cameras and security.	379 (84%)
4	Restrict the number of visitors in the treatment areas.	356 (79%)
5	Efficient coordination with other staff.	397 (88%)

Only 25% of the participants knew The Tamil Nadu Medicare service persons and Medicare services institutions (Prevention of Violence and Damage or Loss to Property Act, 2008). More than half of the participants were unaware of the various sections of The Indian Penal code that can legally protect them during violent acts committed against them (**Table 5**).

**Table 5** Knowledge on the prevailing acts and laws in Indian legislation that legally protects them

Sl. No	Question: Which of the following acts are you aware of?	Frequency (%)
1	The Tamil Nadu Medicare services persons and Medicare services institutions (Prevention of Violence and Damage or Loss to Property Act, 2008).	112 (25%)
2	Indian Penal Codes related to Hurt, Injury and Assault.	198 (44%)
3	Indian Penal Codes related to Defamation	133 (30%)
4	Indian Penal Code related to causing loss to the owner of the property.	188 (42%)
5	Indian Penal Codes related to Outraging the Modesty of a Woman.	165 (37%)

In our study, 95% of the participants were concerned about the prevalence of violence against medical practitioners. About 64% of the medical practitioners knew the medical indemnity insurance policies available. Among the 451 participants, only 25% were prepared to take legal action against the offenders in the event of any violent outbreaks. The participants who hesitated to take any legal action agreed that they had poor knowledge of the legal procedure and lost hope in the judicial proceedings.

## DISCUSSION

Today violence against a doctor is four times more than any other profession. The Indian Medical Association claims that 82.7% of medical practitioners are stressed out. Among them, 46.3% attribute their stress to the fear of violence.<sup>10</sup> Surprisingly, few studies are available about violence against medical practitioners in India. This study includes a blend of medical practitioners across all specialities, working in both private and public sectors with a wide range of experience in their clinical practice. Almost all medical practitioners were worried about the rising trend of workplace violence in India.

Among the 451 medical practitioners across Tamil Nadu, most of the medical practitioners in our study group had a good knowledge of what constitutes a violent act. Almost all of them had good knowledge about preventive strategies of violent outbreaks at their clinical establishments. Only 25% of the participants preferred to inform the police and take legal action against the offenders. 68% of the participants opted to remain calm, convince the troublemakers and solve the issues then and there. Neeraj Nagpal et al in their observation also highlight the above finding.<sup>7</sup>

About the causes of violent outbreaks in healthcare establishments, most participants agreed that misguided conclusions, the unforeseen outcome of treatment, lack of knowledge of legal consequences from a patient's perspective were the leading causes of violence against medical professionals. Literature also highlights similar findings.<sup>11,12</sup> 88% of the medical practitioners agreed that having a good rapport with their patients can prevent violent outbreaks at their workplace. This was comparable to the study conducted by Kesavan R et al.<sup>9</sup> More than 80% of our study population believed that installing Closed Circuit Television (CCTV), restricting visitors and displaying the legal consequences for the offenders and efficiently coordinating with other healthcare workers in handling such situations may prevent further violent outbreaks in hospitals. Gosh K et al. also propose similar ideas to curb violence against medical professionals in their study.<sup>12</sup>

Surprisingly only 25% of the participants were aware of The Tamil Nadu Medicare service persons and Medicare



service institutions (Prevention of Violence and Damage or Loss to Property Act, 2008). Neeraj Nagpal, in their study, also highlights similar findings.<sup>7</sup>

Only 37 to 44% of the medical practitioners who participated in our study knew the legal provisions to protect them. Only 37% of the participants were aware of the Indian Penal Codes regarding Outraging the Modesty of the Women and its punishments. 75% of participants in our study did not prefer to report violent acts committed against them to the police or to take legal action against the offenders. Similar outcomes were observed in other literature also.<sup>11,12</sup>

Workplace violence against health care professionals is offensive, and it affects their psychological and physical well-being and motivation. Such instances may put the quality of care and healthcare provision at risk.<sup>13</sup> Violence against healthcare workers is an underreported, pervasive, and chronic problem that has been primarily tolerated and disregarded, especially when the act is non-physical.<sup>14</sup> Fueled by media, politics, and bureaucracy, people shall never change their attitude and perception towards medical professionals. When it comes to violence against doctors, it's, unfortunately, every man for himself. Hence, apart from helping humanity by healing, the medical fraternities need to update their knowledge on the existing legal statutes about violence against medical professionals.

## CONCLUSION

Most of the medical practitioners in this study were unaware of the Acts and Indian Penal Codes about violence against them. Most of them did not prefer to report any violent outbreaks at their clinical establishment to the police. This attitude of being humble and ignorant need to be changed. They have to remain united and overcome their inhibitions to approach the Police and Court of law in such circumstances.

A good medico-legal education needs to be included in the current competency-based Medical Education system apart from other attitude, ethics, and soft communication skills modules. Good expertise on the laws and legal procedures among Doctors in our country is the need of the hour, which will help break their inhibitions to take a legal path to curb violent outbreaks.

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### RESEARCH PAPER

# Learning curve experience in laparoscopic common bile duct exploration for concomitant cholelithiasis and choledocholithiasis

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**Background and aims:** Laparoscopic common bile duct exploration offers several advantages over endoscopic stone clearance for common bile duct stones with gall stones. However, lack of expertise and a learning curve has often been deterrents to widespread application. This study presents our initial experience and learning curve in managing concomitant cholelithiasis and choledocholithiasis with laparoscopic cholecystectomy (LC) and laparoscopic common bile duct exploration (LCBDE). **Methods:** Between January 2016 and January 2020, a total of 51 selected patients with concomitant cholelithiasis and choledocholithiasis underwent LC and LCBDE, and we reviewed our data retrospectively. The primary outcome measure was the common bile duct (CBD) stone clearance rate. Secondary outcome measures were conversion rate, morbidity, mortality and length of hospital stay. **Results:** A total of 51 selected patients with cholelithiasis and choledocholithiasis underwent LC and LCBDE in a single tertiary care centre over four years. The success rate for laparoscopic stone clearance was 96.07%. The conversion rate was 3.92%. The overall mean duration of the operation was 140 minutes. There was no significant postoperative morbidity and mortality. Hospital stay ranged from 4 to 6 days. **Conclusion:** For concomitant cholelithiasis and choledocholithiasis, LCBDE is a highly successful single-session minimally invasive procedure and safe even for beginners with basic laparoscopic training and facilities in selected patients.

**Keywords:** Cholelithiasis, learning curve, laparoscopic cholecystectomy, choledocholithiasis

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## INTRODUCTION

Approximately 3% to 14.7% of patients with gallstones have concurrent common bile duct (CBD) stones.<sup>1</sup> Because of complications of CBD stones, including pain, biliary

obstruction, cholangitis, hepatic abscesses and pancreatitis, the European Association for Endoscopic Surgery recommends that these patients should be treated even when asymptomatic.<sup>2</sup> Though laparoscopic cholecystectomy (LC)

has become the ‘Gold Standard’ method for cholelithiasis, there is no consensus for managing choledocholithiasis.

With the increase in expertise with endoscopic procedures, preoperative endoscopic retrograde cholangiopancreatography (ERCP) and stone clearance followed by LC has emerged as a widely available and routine procedure for patients with choledocholithiasis and cholelithiasis. But it is a two-stage procedure. Other disadvantages of ERCP are that it is associated with some immediate though rare, life-threatening complications like pancreatitis, bleeding and duodenal perforation, papillary stenosis, and increased risk of bile duct cancer in the future.<sup>3</sup>

With refinements in technical expertise and improvements in equipment in the field of laparoscopic surgery, LCBDE has become a potential option for managing choledocholithiasis simultaneously with LC in a single-stage.<sup>4</sup> A few studies have suggested that this single-stage procedure is not only safe but offers lower morbidity, shorter length of hospital stay and is more cost-effective than the two-stage procedure.<sup>5,6</sup> Further, a recent meta-analysis has shown it to be better than the two-stage procedure in stone clearance.<sup>7</sup>

Though the benefits of a single stage LCBDE seem apparent, the lack of expertise and an uncertain learning curve has often been held as deterrents to its widespread application. Hence, we planned this study to present our initial experience with LCBDE and our learning curve.

## MATERIAL AND METHODS

Between January 2016 and January 2020, in 4 years, a total of 51 highly selected patients with concomitant cholelithiasis and choledocholithiasis underwent LC and LCBDE in a single tertiary care centre by a single surgeon. Consecutively collected data were reviewed retrospectively. As a beginner for LCBDE, we had planned LC and LCBDE in a selected group of patients in a tertiary care centre with an established Department of Gastroenterology where well-equipped and highly experienced Gastroenterologists are available. ERCP and Endoscopic Sphincterotomy (ES) are routinely done here. Patients’ selection criteria were: Uncomplicated cholecystitis in Ultrasonography (USG) with well-delineated CBD stone/stones in Magnetic Resonance Cholangiopancreatography (MRCP), dilated CBD (10/>10 mm), preferably single stone (but up to 3) and stone size of 8/>8 mm. With gaining experience in the later part of the study, we had included some patients where ERCP was not feasible or had failed. One patient with Roux-en-Y gastrectomy 20 years back and four patients with periampullary duodenal diverticulum was included later in the study period. Clinical evidence of cholangitis and biliary pancreatitis was omitted for acute cholecystitis patients.

Institutional board approval was obtained for the study. Informed consent was taken from all patients, and the possibility of conversion to open and postoperative ERCP if indicated. The primary outcome measure was the CBD stone clearance rate. Secondary outcome measures were conversion rate, morbidity, mortality and length of hospital stay.

## Operative technique

After all necessary preoperative workups, all patients received prophylactic antibiotics at the time of induction after a negative skin test. The procedure was performed using a standard four-port technique for LC, with slight variation. The epigastric port was placed a little to the right to maintain maximum alignment with CBD during choledochoscopy. The correct subcostal port was slightly lower, and a fifth port was placed in the left upper quadrant, maintaining the ergonomics for suturing the choledochotomy. LCBDE was done via the transcholedochal route in all patients because of the large stone size. After adequately identifying CBD and removing the anterior peritoneal layer, a longitudinal supraduodenal choledochotomy was made, initially a small nick by the hook than extension by the scissor, which was determined by the largest stone size. Often, stone/stones are extracted with simple manipulation over the duodenum. Otherwise, we used forceful irrigation, first proximal CBD/common hepatic duct (CHD), then distal CBD is irrigated by inserting an 8 French infant feeding tube precisely as done in open surgery. In case of failure, we used a Fogarty balloon catheter. Complete ductal clearance was confirmed by choledochoscopy, and choledochotomy was closed over a T-tube with interrupted 3-0 polyglactin 910 (Vicryl) in all cases. A leak test was done routinely, and an external non-suction tube drain was left in the right subhepatic region, removed on a post-operative day 1 (POD1) if there was no abnormal drain content. We did not do completion cholangiography. The procedure was converted to open if stone clearance could not be achieved laparoscopically. Dindo-Clavien classification was used to stratify the severity of operative and postoperative complications.<sup>8</sup>

## RESULTS

Between September 2016 and September 2020, in 4 years, a total of 51 selected patients with concomitant cholelithiasis and choledocholithiasis underwent LC and LCBDE at our institute. The two surgeons operated on all cases (BPP and MA). Both had less than two years of laparoscopic experience at the beginning of the study, mainly in the form of laparoscopic cholecystectomies.

The male to female ratio of the patients was 4.1:1, with a median age of 42 years (range 24 to 68 years). Most of the

patients present with biliary colic, jaundice and with or without subclinical cholangitis (**Table 1**).

**Table 1** Patients' parameters

Variable	Patients (51)
Age	24 to 68 years
Gender (Male/Female)	41/10
BMI	22-30
ASA	
ASA I	30 (58.82%)
ASA II	12 (23.52%)
ASA III	9 (17.64%)
Hx of biliary pain	51 (100%)
Hx of jaundice	18 (35.29%)
Mean CBD diameter	8-22mm

*BMI: body mass index, Hx: history, ASA: American Society of Anaesthesiology (ASA.)*

All patients underwent elective LCBDE, and CBD was successfully cleared in 49 patients (96.07%) with a 3.92% conversion rate and one patient required hepaticojejunostomy. The first failure was a single large (22mm) impacted stone in the distal CBD. The second failure was stoned with sharp edges. We could not retrieve the stone even after conversion in the first case, so the patient was managed by Roux-Y hepaticojejunostomy. In the second case, out of two, one stone could not be retrieved and during manipulation Fogarty balloon repeatedly ruptured. This was a failed ERCP patient due to a sizeable periampullary diverticulum. The patient was successfully managed by open surgery.

The overall mean duration of the operation was 140 minutes (range, 130–180 minutes). Intraoperative blood loss was minimal(**Table 2**).

**Table 2** Operative parameters

Variable	Patients (51)
LCBDE	51(100%)
CBD clearance	49 (96.07%)
Conversion	2 (3.92%)
Transcholedochal	51 (100%)
T-tube	50 (98.03%)
Operative time	140min (130-180 min)
No of CBD stones	1-3
Stone size	8mm-22mm
Blood loss	20-100 ml
Blood transfusion	0

There were no mortalities and no intraoperative complications. Three patients developed postoperative fever, 3 had a transient elevation of liver enzymes and 2 had umbilical port site infection, and all were managed conservatively.

T-tube has clapped on a post-operative day (POD) three. During the hospital stay, patients were assessed clinically and by laboratory evaluation. The median length of hospital stay was four days. All patients were discharged home with clamped T-tube in situ, except one who underwent hepaticojejunostomy. T tube was removed on POD21 after a cholangiography showed no filling defect and free passage of contrast into the duodenum.

The mean follow-up was 9±3.4 months (6–54 months). No patients showed retained or recurrent stones, CBD stricture or cholangitis by clinical, laboratory and imaging studies.

## DISCUSSION

Approximately 3% to 14.7% of patients with gallstones have concurrent common bile duct (CBD) stones and require treatment even when they are asymptomatic because of unpredictable complications. Options for management include open cholecystectomy with open CBD exploration, LC with pre-or post-operative ERCP, LC with LCBDE, and Laparoendoscopic rendezvous procedure. Among the methods, pre-operative ERCP and stone clearance followed by LC is the most popular procedure. However, this has its disadvantages; being a two-stage procedure, it is associated with higher costs and more extended hospital stay.

The introduction of LCBDE overcame the drawbacks of both two-staged ERCP with LC procedure and open CBD exploration.<sup>9,10</sup> However, the adoption of LCBDE has been relatively slow because of the anticipated requirement of the high level of technical expertise with laparoscopy and its instrumentation and fear of a long learning curve.<sup>11,12</sup>

The authors of this study did not have a long laparoscopic experience before this study (less than two years each). In the initial stage of the study, we included only selected patients. Gradually in the latter half of the study period, we were able to accept a broader range of patients, including those who had been intervened before. However, the senior surgeon (B.P.B.) had vast exposure to open surgery, which helps reduce the learning curve for laparoscopic surgery. Further, this study shows that very few cases are required to cross the learning curve if the surgeon has the essential laparoscopic experience, as in our case.

Interestingly, we didn't have any conversions in the first 28 cases. As discussed, the first conversion was on the 29<sup>th</sup> case, and the second was on the 43<sup>rd</sup> case. This also shows that, with selected patients and essential laparoscopic



experience, one can safely and successfully offer LCBDE to patients.

This study did LCBDE via the transcholedochal route because of the large stone size. The CBD clearance rate was 96.07%. The conversion rate was 3.92%, comparable to other studies.<sup>13, 14</sup> As a beginner in LCBDE, choledochotomy was closed over a T-tube to provide biliary decompression in all patients and prevent leaks. However, the literature suggests that primary closure with or without stenting is feasible and safe.<sup>15</sup> Complete ductal clearance was confirmed by intra-operative choledochoscopy, which is better and less time consuming than intra-operative cholangiogram.<sup>16</sup> Though this requires an initial investment in a choledochoscope, it is valid and saves on the cost of a C-arm and radiation risk. Other authors have used a nephroscope or cystoscope for the same purpose, reducing the costs of additional instruments. The median length of hospital stay was three days with low morbidity and without mortality, again commensurate with other studies.<sup>6,13,14</sup>

Though mean follow up was 9±3.4 months (6–54 months), usually, due to the extremely low incidence of delayed complications, LCBDE does not justify routine long-term follow-up.<sup>6</sup>

**Limitations:** This study's limitation is that it is a retrospective study in a selective group of patients and is therefore susceptible to selection bias. However, it is always advisable to select patients when starting a new procedure and include all-comers as experience grows, and this is what we have also done.

## CONCLUSIONS

Very few studies have looked at the safety and efficacy of LCBDE during the learning curve. This is one of the few studies presenting data on the safety and effectiveness of LCBDE during the learning curve in India. LCBDE is a highly successful, single-session minimally invasive procedure for patients with concomitant cholelithiasis and choledocholithiasis, which is safe and cost-effective even in novice laparoscopic surgeons' hands with basic laparoscopic training and proper patient selection.

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## International Journal of Health Research and Medico-Legal Practice

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### RESEARCH PAPER

# Early laparoscopic intervention in acute cholecystitis: a hospital-based study

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**Background and aims:** The early timing of surgery in acute cholecystitis remains undefined. Laparoscopic cholecystectomy has become the standard treatment for gall stones but is associated with an increased conversion rate in acute cholecystitis. The present study aims to assess the optimal timing of Laparoscopic cholecystectomy in acute symptomatic cholecystitis with cholelithiasis. **Methods:** Patients attending surgical emergency of our hospital between January 2018 to September 2019 for acute pain abdomen and diagnosed as acute cholecystitis by ultrasonography and haematological examination and who underwent laparoscopic cholecystectomy were recruited. Diagnosis, duration of symptoms, the timing of surgery, outcome, post-operation stay, complications, and conversion rates were recorded. **Results:** A total of 60 patients who attended the surgical emergency underwent laparoscopic cholecystectomy. The surgical procedures were performed within 72 hours in 30 cases and after 72 hours in another 30 cases. Relating to interval from onset of symptoms to surgery, conversion rates for lapchole were 6/30(20%) in < 72 hours and 9/30 (30%) in > 72 hours. Complications ranged from bleeding to bile duct injuries in 1 case. **Conclusion:** Operative intervention for acute cholecystitis is best achieved within 72 hours and can also be done after that period. Conversion rate increases as the timing of intervention increases.

**Keywords:** Laparoscopic cholecystectomy, acute cholecystitis, abdominal pain, murphy's sign.

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### INTRODUCTION

The role of laparoscopic cholecystectomy in acute cholecystitis is controversial. Cholecystectomy is a common procedure for treating acute cholecystitis. Despite the efficacy of laparoscopic cholecystectomy as an elective treatment for symptomatic gallstones, acute cholecystitis was once thought to be a contraindication for the procedure due to technical difficulties and the risk of the development of complications.<sup>1</sup> It has been associated with considerable morbidity, and the reported conversion rate is higher than that for non-acute cholecystitis.<sup>2,3</sup> The ideal timing of surgery in acute cholecystitis remains undefined.<sup>3,4</sup>

Acute cholecystitis is a gallbladder inflammatory illness reported 3%–10% among patients with abdominal pain.<sup>5</sup> As a major complication of gall stones, it is diagnosed in 10 to 30% of cases admitted for cholecystectomy.<sup>4,6</sup> In acute cholecystitis, adhesions alter the anatomy near Callot's triangle. As a result, cholecystectomy for this condition is time-consuming, technically challenging, and associated with increased morbidity.<sup>7</sup> In the pre-laparoscopic era, patients of acute cholecystitis were initially treated conservatively so that the inflamed gall bladder "cools down", followed by cholecystectomy six weeks later. In 1966, D.M.Essenhigh reported that early open cholecystectomy for acute

cholecystitis is as safe as delayed cholecystectomy with reduced morbidity and Hospital stay.<sup>8</sup>

There is a 20-22% failure rate of conservative treatment patients, leading to the development of early complications requiring an urgent and technically demanding cholecystectomy. Moreover, another 10-20% of cases are readmitted with recurrent symptoms and undergoes an unplanned emergency cholecystectomy. A small proportion of cases (10%) develop other complications like slippage of stones into the common bile duct (CBD), making the patient undergo a more extensive operation and possible pancreatitis.<sup>9-12</sup>

Due to the increasing expertise and availability of equipment and to overcome the shortcomings in conservative treatment, the indications of laparoscopic cholecystectomy were extended to include patients with acute cholecystitis. Several studies have documented the feasibility and safety of early laparoscopic cholecystectomy<sup>9,11,13-15</sup>

The present study aimed to determine the optimal timing of surgery in acute symptomatic cholecystitis with cholelithiasis.

## METHODS

This prospective comparative study included all consecutive patients who underwent early cholecystectomy for acute cholecystitis at the Gauhati Medical College Hospital between January 2018 and September 2019. All patients were admitted on an emergency basis. Patients were informed in detail about the procedure, and informed consent was obtained. Hospital ethical committee permission was taken for the study.

The diagnosis of acute cholecystitis was made by clinical examination, laboratory tests, and ultrasonography (USG). The diagnosis criteria for acute cholecystitis were patients with acute upper abdominal pain and positive murphy's sign, fever > 38°C, USG findings of the thick-walled gallbladder with pericholecystic fluid and gallstones and histological evidence of acute cholecystitis, along with white blood count of >12x10<sup>9</sup>/L.

Patients who had no gallstones, not operated on or had obstructive jaundice, ascending cholangitis, biliary pancreatitis were excluded from the study. Those who had incomplete data were also not included.

The study included 60 cases, and patients were randomly divided into two groups depending on the duration of symptoms before surgery, i.e. Group A: symptoms < 72 hours and Group B: symptoms > 72 hours. These groups were analysed to precisely determine the optimum timing for cholecystectomies in acute cholecystitis.

## RESULTS

Demographic profile of the patients: A total of 60 laparoscopic cholecystectomies for acute cholecystitis were performed during the study period. The Male: Female ratio was 1:2.9, and the female age group was younger than that of male patients (42.3-47.7 years vs 52.7-58.9 yrs).

The patients were divided into 30 cases each depending upon the timing of surgery from the onset of symptoms. The mean ± s.d. of patients in Group A was 42.8 ± 9.86 and in Group B was 45.7 ± 7.52, and the difference was not statistically significant.

Clinical profile of the patients: All patients were diagnosed with upper abdominal pain. Fever was present in 15 patients in Group A and 13 patients in Group B. Out of 60 patients, 18 patients in Group A and 15 patients in Group B suffered from Nausea/vomiting. However, no statistically significant difference was observed between the two groups (**Table 1**).

**Table 1** Clinical diagnosis of patients undergoing laparoscopic cholecystectomy for acute cholecystitis

Clinical Diagnosis	Group A	Group B	p-value
Upper abdominal pain	30 (100.0%)	30 (100.0%)	1.0
Positive murphy's sign	16 (53.3%)	19 (63.3%)	0.43
fever > 38°C	15 (50.0%)	13 (43.3%)	0.60
Jaundice	0	0	-
Nausea/Vomiting	18 (60.0%)	15 (50.0%)	0.43

USG profile of patients: All patients in both groups were diagnosed with gallstones in USG. Also, most of the patients in both groups were analysed with thickened and distended gallbladders (**Table 2**).

**Table 2** USG profile of the patients

USG diagnosis	Group A	Group B
Thickened gallbladder	21 (70.0%)	18 (60.0%)
Distended gallbladder	18 (60.0%)	19 (63.3%)
Presence of gallstones	30 (100.0%)	30 (100.0%)
Pericholecystic fluid	12 (40.0%)	11 (36.7%)

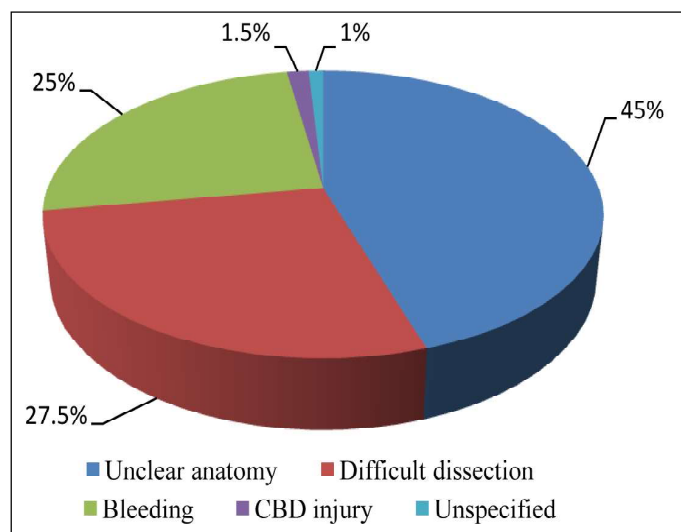
Laparoscopic cholecystectomy was successful in 80% of cases if done within 72 hours of symptom onset and in 70% if done after 72 hours. Conversion rates were 20% and 30%, progressively indicating that it depended on the timing of surgery. The duration of hospital stay was longer among patients undergoing laparoscopic cholecystectomy after 72 hours (**Table 3**).



**Table 3** Procedures performed in patients with symptomatic cholelithiasis and timing of surgery

Timing of surgery.	Lap chole attempted	Lap chole converted	Mean hosp. Stay(days.)
Group A	30	6(20%)	2-3.
Group B	30	9(30%)	4-5.

The reason for conversion in 45% of the patients was unclear anatomy, while 25% of the modifications were done due to bleeding. There was one case of CBD injury following laparoscopic cholecystectomy after 72 hours, requiring Hepatico-jejunostomy later (**Figure 1**).

**Figure 1** Reasons for conversion from laparoscopic to open cholecystectomy

## DISCUSSION

Even though laparoscopic cholecystectomy has become the gold standard for treating symptomatic gall bladder disease, minimally invasive surgery's role in treating acute cholecystitis is still debatable. This condition used to be considered a contraindication to laparoscopic cholecystectomy. Growing experience with laparoscopic cholecystectomy has led to its usage in acute cholecystitis, with good results in recent years. Based on a limited period audit of cholelithiasis management in our institution, this research discusses the role of early intervention in a diagnosed case of acute symptomatic cholecystitis.

The results of this study are consistent with recently published data which shows that early laparoscopic cholecystectomy in Acute cholecystitis is safe, with similar conversion rates.<sup>6,9,15,16</sup> Early cholecystectomy results in significantly shorter hospital stay and avoids the risk of failed conservative treatment.<sup>15,17</sup> Despite the positive outcomes, acute cholecystitis is still considered a potential risk factor of conversion and laparoscopic cholecystectomy complications.<sup>12</sup>

Many authors advocate early surgery as waiting for surgery often leads to cost escalations due to hospital stay and increased complications in delayed surgery after 72 hours of symptom onset.<sup>18,19</sup> Uchiyama and colleagues in Japan highlighted the role of clinical pathways in reducing hospital stay and the cost of laparoscopic surgery.<sup>20</sup>

In the present study, the complication rate is generally acceptable, with most complications, including the single CBD injury were limited to the latter time of intervention (>72 hours). These findings point to the importance of early intervention in acute cholecystitis.

Based on the ongoing global research on the topic and the present study's findings, it may be advocated to initiate an early intervention for acute cholecystitis within 72 hours after admission. Surgical intervention is technically less demanding during that period because the oedema planes magnify the structures and facilitate dissection. The morbidity and growing cost of waiting for surgery after conservative treatment of initial admission is a compelling argument favouring early intervention in acute cholecystitis.

## CONCLUSION

In acute cholecystitis, early intervention by laparoscopic cholecystectomy, performed within 72 hours of admission, is safe and associated with less mortality and morbidity and lesser hospital stay. However, intervention can be done after 72 hours of initial symptoms, but the golden period of 72 hours after admission gives the best possible results.

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### RESEARCH PAPER

# Burden and commonest cause of sudden natural death among medicolegal autopsies in a tertiary care centre: a retrospective study

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**Background and aims:** Sudden natural death that occurred apparently to a healthy individual sometimes creates suspicions of foul play, thus subjected to medicolegal (ML) examinations. The present study aims to determine the age and sex-specific burden and identify the most typical cause of sudden natural death in ML autopsies at a tertiary care hospital. **Methods:** A retrospective study were conducted in the Department of Forensic Medicine, Gauhati Medical College & Hospital, Guwahati, Assam, including all autopsy cases of sudden natural death conducted from Jan 1, 2018, to Dec 31, 2018. The death circumstances were analyzed from the inquest report and hospital cause of death certificate. The distribution of the cases concerning various socio-demographic variables was presented as frequencies and percentages. The data were analyzed using Statistical Package for the Social Sciences (SPSS) version 16. **Results:** Out of the total of 3574 autopsies, 243 (6.8%) were sudden natural deaths, with a male predominance of 82.2%. Maximum deaths occurred in the age group of 31 to 40 years (32.92%). The present study affected the married individuals (181/243) and urban residents (68.34%). The cardiovascular (45.27%) and gastrointestinal systems (20.16%) were the most common organ system involved. Among the cardiac causes, chronic coronary insufficiency was the most common cause (34.16%). **Conclusion:** Cardiac causes were the most typical cause of sudden natural death, particularly among the young. Medicolegal examinations can solve most of the doubts arising out of sudden natural death.

**Keyword:** Sudden death; autopsy; cardio-vascular; cause of death.

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### INTRODUCTION

Death is an inevitable occurrence in the life of every person. Every human being wants to die naturally and peacefully. But sometimes, sudden death that occurred apparently to a healthy individual may raise many questions and create

suspicion among the near and dear ones of foul play. Such incidents are most shocking and unexpected. Sudden natural deaths occupy a significant portion of deaths undergoing autopsy.<sup>1</sup> As in case of sudden natural deaths, it is not usually possible to identify the cause of death by external

examinations of the body, forensic medicine experts play a vital role in differentiating natural deaths from unnatural deaths and establishing an association of diseases with work, behaviour, trauma or any other events.<sup>2</sup>

A death that is not known to have been caused by any trauma, poisoning or violent asphyxia and occurs suddenly or within 24 hours of the onset of terminal symptoms is defined as sudden death.<sup>3</sup> According to the World health organization (WHO), sudden death is an unexpected non-violent death of a person usually seen within 24 hours of the onset of symptoms.<sup>4</sup> Whereas, death occurring due to some natural diseases or pathological conditions where the death is not intended or attempted is attributed as a natural death.<sup>5</sup> There is frequent or unexpected deaths with natural deaths, but sudden death is not always natural and vice versa. An autopsy can differentiate sudden natural death from sudden unnatural death.

Most reported causes of sudden natural deaths are related to the cardiovascular system followed by respiratory, neurological, digestive, infectious and genito-urinary conditions.<sup>6,7</sup> Almost 40-50% of cardiovascular deaths are accounted for sudden cardiac deaths.<sup>8</sup> As per the centre for global health research, cardiovascular diseases are the leading cause of death in India.<sup>9</sup> Annually, an estimated 7 lakh sudden cardiac deaths occur in India.<sup>10</sup> Studies suggest that unevaluated ischemic heart disease is the most significant cause of sudden cardiac deaths in developed countries.<sup>7,10</sup>

The northeastern region of India constitutes diverse ethnic-tribal demography with varied lifestyles and food habits. However, studies on morbidity and mortality pattern are limited in this part of the country.<sup>11</sup> Many studies are not available on the prevalence and cause of sudden natural deaths in northeast India.

The present study was undertaken to study the burden of sudden natural deaths among medicolegal autopsies in a tertiary care centre. The study aims to assess the socio-demographic profile of the sudden natural death cases brought for medicolegal autopsy and identify the commonest accountable cause of sudden natural death.

## MATERIALS AND METHODS

The study was conducted retrospectively in the Department of Forensic Medicine, Gauhati Medical College & Hospital (GMCH), Guwahati, Assam taking all the cases of autopsy having the opinion of sudden natural death a cause of death from Jan 1, 2018, to Dec 31 2018.

All the cases of autopsy having the opinion of natural death as a cause of death and cases brought dead in casualty without evidence of unnatural cause were included. Unnatural death cases, unknown cases, natural death cases

with recorded chronic illness, poisoning and decomposed cases were excluded. The death circumstances were analyzed from the inquest report and hospital cause of death certificate. All instances of sudden natural death were analyzed irrespective of age and sex.

The distribution of the cases concerning various socio-demographic variables was presented as frequencies and percentages. The data were analyzed using Statistical Package for the Social Sciences version 16. Ethical clearance for the study was obtained from the Institutional Ethics Committee of Gauhati Medical College and Hospital, Guwahati, vide no. MC/190/2007/Pt-11/Jan-2019/10.

## RESULTS

During the study period total of 3574 cases were brought for medicolegal autopsies to GMCH mortuary, out of which 243 cases were found to be sudden natural death constituting an overall burden of 6.8%.

Male predominance was observed among the sudden death cases as out of 243 cases, 195 cases (82.2%) were male, and 48 cases were female with a sex ratio of 4:1.

The age and gender distribution of the cases showed that most of the cases were reported from the adult age group and the commonly involved age group was 31 to 40 years (32.92%) followed by 41 to 50 years (30.86%) in both male and female. One case of sudden natural death was reported from the lowest age group of 0-10 years and the highest age group of 80-90 years. The majority of the cases were married (74.4%), as shown in **Table 1**.

**Table 1** Age and gender-wise distribution of cases

Age group	No. of cases (n=243)	Percentage (%)	Male (n=195)	Percentage (%)	Female (n=48)	Percentage (%)
0-10	1	0.41	1	0.41	0	0
11-20	7	2.88	6	2.47	1	0.41
21-30	34	13.99	27	11.11	7	2.88
31-40	80	32.92	64	26.33	16	6.58
41-50	75	30.86	60	24.69	15	6.17
51-60	30	12.35	23	9.47	7	2.88
61-70	10	4.12	9	3.70	1	0.41
71-80	5	2.06	4	1.65	1	0.41
80-90	1	0.41	1	0.41	0	0
>90	0	0	0	0	0	0
Marital status						
Married	181	74.4	142	72.8	39	81.2%
Unmarried	48	19.7	43	22.0	5	10.4
Status not known	14	5.8	10	5.2	4	8.3



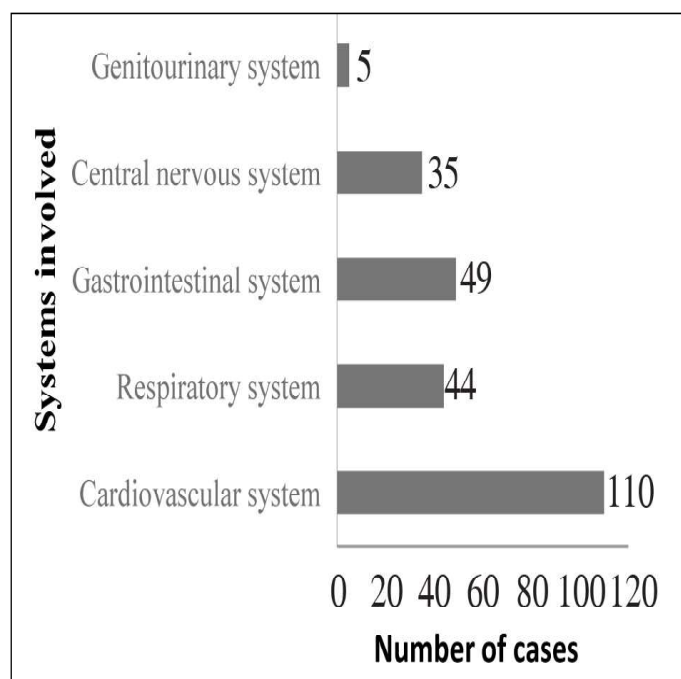
Sudden death is more common among the cases brought from urban residential areas, with 167 out of 243 cases (68.7%). The majority of the cases were average body mass index (BMI) with 153 (63.0%) cases. Out of the 243 cases, 24.3% (59/243) were obese, and only 12.7% had low BMI.

**Table 2** Distribution of cases according to the place of death

Place of death	Number of cases (n=243)	Percentage (%)
Brought dead	131	53.9
Hospital	34	14.0
Roadside	8	3.3
Home	70	28.8

Among all cases, 53.9% of cases were brought dead to the hospital (**Table 2**).

Among the causes of sudden death, the most commonly involved organ system was the cardiovascular system (45.27%), followed by the gastrointestinal system (20.16%), respiratory system (18.11%), central nervous system (14.4%) and genitourinary system (2.06%), as shown in **Fig. 1**.



**Fig. 1** Distribution of cases according to involved organ system

Among the cardiac causes, chronic coronary insufficiency is the most common cause (34.16%). Cardiac tamponade was observed in 2 (0.82%) cases. Among the gastrointestinal causes, chronic liver disease (13.58%) was reported in most cases. While among the respiratory causes, pneumonia (11.11%) was mainly observed (**Table 3**).

**Table 3** Distribution of cases according to various types of the cause of death

System		Disease	Number of cases	The percentage among total sudden death	The percentage among total autopsies
Cardio-vascular	110	Chronic coronary insufficiency	83	34.16	3.08
		Cardio-myopathy	25	10.29	
		Cardiac tamponade	2	0.82	
Gastro-intestinal	49	Chronic liver disease	33	13.58	1.37
		Rupture of oesophageal varices	7	2.88	
		Acute haemorrhagic pancreatitis	5	2.06	
		Intestinal perforation	4	1.65	
Respi-ratory	44	Pneumonia	27	11.11	1.23
		Tuberculosis	17	6.70	
Central nervous	35	Spontaneous intracranial haemorrhages	35	14.40	0.98
Genito-urinary	5	Chronic parenchymal disease of kidneys	5	2.06	0.14

## DISCUSSION

Deaths of unnatural, suspicious and unexpected manner necessitate an autopsy as a portion of the evidence-gathering process.<sup>12</sup> In sudden death investigation, sequential autopsy examination investigates the underlying cause of death and answers the suspicion of foul play regarding those unexpected deaths.<sup>13</sup>

Among 3574 autopsies during the study period, 243 were sudden natural deaths implying an overall burden of 6.8%. Other studies from northeast India reported the incidence of sudden natural death of 8.6% to 9.2%.<sup>14,15</sup> Meanwhile, the incidence of sudden natural death in other parts of India is reported as low as 0.74 to as high as 13.5%.<sup>1,2,16-18</sup>

Among all cases, males are seen to be affected mostly (80.2%) with an M: F ratio of 4:1. Male predominance in sudden natural deaths was observed in many other similar studies from India and around the globe.<sup>2,7,15,18-22</sup> The majority

of the deaths were observed among married males and from urban areas. A recent study reported marriage dissatisfaction as a significant risk factor of sudden cardiac deaths among males.<sup>23</sup> Urbanization as a factor of cardiovascular mortality was reported in a study from Brazil.<sup>24</sup> This might be due to an increasingly sedentary and stressful urban lifestyle.

Maximum cases of sudden death in both sexes were in the 31 to 40 years age group followed by 41-50 years. Several studies reported a higher incidence of sudden natural deaths among young adults in the 30-50 years age zone.<sup>1,2,18,22,25</sup>

Most cases were reported in average BMI persons (62.96%), followed by obsessed persons. A similar finding was observed in the study of Tyagi et al.<sup>26</sup> According to the present study; most cases were brought dead to the hospital (53.91%) followed by death at home (28.81%). The majority of sudden natural deaths occurring outside the hospital setting was concordant with a review.<sup>27</sup>

The majority of the sudden natural deaths in the present study was related to the cardiovascular system (45.27%). Various studies reported cardiac origin as the most common cause of sudden deaths in both genders, specifically among the adult male population.<sup>19,20,22,28,29</sup> Chronic coronary artery disease was the most reported cardio-vascular ailment (34.16%). The finding is in agreement with some other studies.<sup>2,19,22,25</sup>

Several studies<sup>2,20,22,28,30</sup> reported respiratory system ailments as the second prevalent cause of sudden death; however, in the present study, gastrointestinal system problems, particularly chronic liver diseases (13.58%), were reported second most cause of death. Pneumonia was the most common respiratory cause (11.11%). The cause of death in the only child below ten years old is pneumonia. Pneumonia is considered the prime cause of death among children below five years, accounting for almost 16% of child deaths.<sup>31</sup>

## CONCLUSION

The present study reveals that cardiac causes are the most common cause of sudden natural death among the adult population in the study site. Increased frequency of sudden deaths among urban, married and adult male populations might be due to sedentary lifestyles in urban areas and increased stress among married individuals due to workload and family responsibilities, indicating a physical and mental disequilibrium in modern times resulting in this type of unexpected deaths. A thorough postmortem and histopathological examination can solve most of the doubts arising from sudden death among the common population.

**Conflict of interest:** No conflict of interest is associated with this work.

## Contribution of authors:

- (1) The article is original with the author and does not infringe any copyright or violate any other right of any third party.
- (2) The article has not been published (whole or in part) elsewhere and is not being considered for publication elsewhere in any form, except as provided herein.
- (3) All authors have contributed sufficiently in the article to take public responsibility for it and
- (4) All authors have reviewed the final version of the above manuscript and approved it for publication.

**Ethical clearance:** Taken.

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### RESEARCH PAPER

# Laparoscopic cholecystectomy in rural setup

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**Background and aims:** Cholelithiasis or gall stone disease is a significant healthcare problem among the adult population. Laparoscopic cholecystectomy is widely accepted as the gold standard in symptomatic gall stone diseases. However, common bile duct injury is more frequent in laparoscopic cholecystectomy than open cholecystectomy. The present study audits 184 laparoscopic cholecystectomy patients in Tezpur Medical College from August 2014 to September 2019. This study aims to determine the advantages, intra-operative and postoperative complications in laparoscopic cholecystectomy and assess the reasons for conversion to open cholecystectomy. **Methods:** The retrospective study consists of 184 patients with symptomatic cholelithiasis/chronic cholecystitis and treated by standard four-port laparoscopic cholecystectomy from Aug'2014 to Sept'2019 at Tezpur Medical College. The results and complications of laparoscopic cholecystectomy were documented for each case and were analysed. **Results:** Out of the 184 cases, 139 were females. The age of the patients ranged from 14 to 65 years. The average duration of operating time was 65 minutes. Conversion to open cholecystectomy was 3.2%. There were no postoperative abdominal abscesses, port site hernia, or mortality cases. There were two bile duct injuries. One patient with lateral damage to the common bile duct was managed by open repair, and the other subject reported later was referred to a higher centre. **Conclusion:** Laparoscopic cholecystectomy in our set-up proves to be a safe procedure and effective treatment of Gallstone diseases.

**Keywords:** Gallstone diseases, Open Cholecystectomy, Laparoscopic Cholecystectomy, Rural setup.

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## INTRODUCTION

Cholelithiasis or gall stone disease is a significant healthcare problem affecting 10% to 15% of the adult population in developed societies.<sup>1</sup> Although gall stones are common, most of the cases are asymptomatic.<sup>2</sup> In symptomatic gall stone diseases, laparoscopic cholecystectomy is widely used as the procedure is less invasive and has a lower surgical risk than conventional open surgery. However, common bile duct injury is more frequent in laparoscopic cholecystectomy than open cholecystectomy.

In 1882, Carl Langenbuch performed the first cholecystectomy enunciating a principle "The gall bladder

needs to be removed not because it contains stones but because it forms them".<sup>3</sup> Open cholecystectomy has long been considered the gold standard in the treatment of gallstones. The first laparoscopic cholecystectomy was performed on September 12, 1985, by Prof Dr Med Erich Mühe of Böblingen, Germany.<sup>4</sup> First documented laparoscopic cholecystectomy using a keyhole approach was by Philip Mouret of Lyon, France, in 1987.<sup>4</sup> Since then, laparoscopic cholecystectomy has become the preferred treatment for gallstones. Preferences and desire for laparoscopic cholecystectomy are logical in today's environment because it causes less pain, requires less medicine, requires a shorter hospital stay, allows for an



early return to regular work and activities, and offers good cosmetic outcomes. Also, this technique provides a minimally invasive surgical alternative to open cholecystectomy. However, as documented in various studies, laparoscopic cholecystectomy necessitates the surgeon's use of two-dimensional vision and tactile tissue perception, resulting in 0.4% to 0.6% bile duct injuries. While in open cholecystectomy, common bile duct injuries encounter up to 0.3% cases.<sup>5</sup>

Tezpur Medical College is a new set-up. It lacks some facilities such as Endoscopic Retrograde Cholangiopancreatography (ERCP), Intraoperative Cholangiogram, Magnetic Resonance Cholangio Pancreatography (MRCP), etc. Also, it is situated 18 Kilometres away from the town. The patients attending the hospital are usually from the surrounding villages and far remote areas. Most of them are unaware of modern medical procedures and often needs to be counselled. In the present study, we have tried to assess the applicability and safety of laparoscopic cholecystectomy in this rural medical setup.

The objective in the present study is to assess the applicability and safety of the laparoscopic cholecystectomy in a rural hospital set up in terms of duration of surgery, analgesic requirements, postoperative complications, conversion to open cholecystectomy, postoperative hospital stay and time taken for return to normal work.

## MATERIAL AND METHOD

This study consisted of 184 patients diagnosed with cholelithiasis/chronic cholecystitis with at least one attack of abdominal pain, i.e. symptomatic gall stones and underwent laparoscopic cholecystectomy at Tezpur Medical College from August 2014 to September 2019.

**Inclusion Criteria:** Patients with cholelithiasis proven by Ultrasound scanning with at least one attack of upper abdominal pain and considered fit for elective cholecystectomy were included.

**Exclusion criteria:** The patients who had a history or images suggesting common bile duct stones, perforated gall bladder or testing positive for hepatitis B or C are excluded from the study. Also, patients over 70 years of age were not included in the study.

All patients have been admitted after preoperative workup including blood counts, sugar, renal function test, thyroid-stimulating hormone, viral profile (Hepatitis B and C, HIV), ultrasound abdomen to confirm Gall stones and to assess the common bile duct diameter, chest X-ray and ECG were done then with all reports pre-anaesthetic check-up was performed. Patients who opted for laparoscopic

cholecystectomy were explained the possibility of conversion to open cholecystectomy. All the cases were elective. A 3rd generation cephalosporin IV dose was given preoperatively after the skin test. Injectable Gentamycin or Amikacin and Analgesics were given 2 to 3 days postoperatively, then orally for three days. Patients were started oral feeding between 24-48 hours postoperatively. Patients were discharged on the 3<sup>rd</sup> to 5<sup>th</sup> postoperative day. Sutures were removed on 7 to 8<sup>th</sup> postoperative day. Patients were reviewed on the 7<sup>th</sup> and 21<sup>st</sup> days after discharge. Follow up was done for 3-6 months whenever possible. Standard 4 port techniques were used. The pneumoperitoneum was created by open method using blunt trocar (Hason's procedure).

## RESULTS

The total number of patients admitted for laparoscopic cholecystectomy was 184, out of which 24.4% were males. The mean age of the patients was 39 years. The average duration of operation time was 65 minutes. More time was required due to intraoperative CO<sub>2</sub> leak, calots triangle dissection, spillage of stones, slippage of clips and delivery of gall bladder through the port site. Most patients (92.9%) stayed in the hospital for less than five days (**Table 1**).

**Table 1** Patient profile

Variable	Category	Observations
Gender	Male	45 (24.4%)
	Female	139 (75.6%)
Age-group	0-20	15 (8.1%)
	21-30	66 (35.9%)
	31-40	59 (32.1%)
	41-50	26 (14.1%)
	51-60	15 (8.1%)
	61-70	3 (1.6%)
Operative time duration	Range: 40-90 minutes	Average: 65 minutes
Hospital stay (in days)	Less than or equal to 5	171 (92.9%)
	5-10	9 (4.9%)
	More than 10	4 (2.2%)

2 (Two) patients had bile duct injuries. One patient had lateral bile duct injury due to clip advancement and having biliary stricture, which was managed with stent placement outside and later exploration and end to end anastomosis. Another patient reported after four weeks, referred to a higher centre as per the wish of the party where he was operated on. (**Table 2**).

**Table 2** Intra and postoperative complications

Complications	Number	Percentage
Bile duct injury	2	1.08%
Perforation of GB with stone spillage	7	3.8%
Haemorrhage	6	3.3%
Bile leak	5	2.7%
Wound infection	7	3.8%
Chest infection	3	1.6%

As seen from **Table 3**, Six (3.2%) patients had to convert from laparoscopic to open cholecystectomy in the initial period. Five patients were converted due to dense adhesion in the fudus body and calots area, probably due to post-acute cholecystitis and empyema of the gallbladder. One patient had inadvertent hook cautery injury to the cystic artery with profuse bleeding.

**Table 3** Conversion rate from laparoscopic to open cholecystectomy

Series	Conversion rate (%)
Saeed et al. <sup>6</sup>	3.2
Wherry et al. <sup>7</sup>	8.08
Simpoulous et al. <sup>8</sup>	5.2
Shiazaki et al. <sup>9</sup>	6.4
Elder et al. <sup>10</sup>	12.5
Cheema et al. <sup>11</sup>	2.0
Mir I S et al. <sup>12</sup>	1.8
This Study	3.2

## DISCUSSION

Laparoscopic cholecystectomy is one of the most commonly performed laparoscopic procedures. It requires only 0.5 to 1 cm incisions that cause relatively less pain, early ambulation, shorter hospital stay, early return to work, early return of intestinal motility and lower incidence of incisional hernia. Surgeons and patients now prefer laparoscopic cholecystectomy to open cholecystectomy as the procedure is cost-effective and produces less morbidity. Access to laparoscopic cholecystectomy is equally vital for rural communities of the developing world.

The present study revealed the need for conversion from laparoscopy to open cholecystectomy in 3.2% of patients, comparable to a study from Pakistan.<sup>6</sup> Wherry DC et al.<sup>7</sup> evaluated complications of laparoscopic cholecystectomy performed in medical treatment facilities of the Department of Defence and reported conversion to open cholecystectomy in 8.08% patients with bile duct injury in 0.57%. In the present study, bile duct injury was observed in 1.1% of patients. Simpoulous C et al.<sup>8</sup> reported conversions to open cholecystectomy in 5.2% of patients, while Elder S et al.<sup>10</sup>

reported a 28% conversion rate in their study. Mir IS et al.<sup>12</sup> reported a conversion rate of 1.8% in a prospective analysis conducted in a non-teaching hospital in the rural area of Kashmir.

Laparoscopic cholecystectomy is an invasive procedure associated with a range of minor and major complications. The present study found gallbladder perforation with stone spillage, bile duct injury, haemorrhage, bile leak, and wound infection as the most frequent complications of laparoscopic cholecystectomy. Damage to the main bile duct is more frequent with laparoscopic cholecystectomy.<sup>13</sup> In this study, one patient with lateral bile duct injury due to clip advancement and having billiary stricture was managed with stent placement outside and later exploration and end to end anastomosis. One should be cautious because most bile duct injuries are not visible intra-operative and present in the postoperative period. Successful performance of laparoscopic cholecystectomy requires proper training, discipline, skill and technology and ongoing maintenance of competency.<sup>12</sup>

Duca S et al.<sup>14</sup> reported the most frequent complications of laparoscopic cholecystectomy as bile leakage, haemorrhage, subhepatic abscess and retained bile duct stones. Ghnnam W et al.<sup>15</sup> reported postoperative transient pyrexia, wound infection, fluid collection and bile duct injury as the common complications in their study. Deziel DJ et al.<sup>16</sup> conducted a national survey of 4292 hospitals and 77604 cases of laparoscopic cholecystectomy and reported that bile duct injuries were recognised postoperatively in half of the cases and most frequently required anastomotic repair, while bowel and vascular injuries which occurred in 0.14% and 0.25% cases respectively were the most lethal complications and postoperative bile leak in 0.3% of patients most commonly originating from the cystic duct.

Despite the advantages of laparoscopic cholecystectomy, possible injuries and postoperative complications are still of concern. The effective administration of the procedure depends upon the proper training and expertise of the surgeon and the quality of the types of equipment used. The present retrospective study revealed a low incidence of bile duct injury and a high success rate among the patients who have undergone laparoscopic cholecystectomy at our institute.

## CONCLUSION

With a high success rate of 97%, laparoscopic cholecystectomy may be considered a safe and effective treatment for symptomatic cholelithiasis/chronic cholecystitis at our set-up. The findings of the study are comparable to similar other studies. However, the procedure may result in bile duct injuries and other postoperative complications.

Hence, preventive and safety measures and proper training of the performing surgeon are necessary prerequisites for effectively utilising the procedure.

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### RESEARCH PAPER

# Management of endoscopic retrograde cholangiopancreatography (ERCP)-related perforations in a tertiary care centre in North-East India

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**Background and aims:** Endoscopic retrograde cholangiopancreatography (ERCP) related perforations are rare complications but are associated with significant morbidity and mortality. The purpose of this retrospective study was to evaluate the management and outcomes of these perforations. **Methods:** The study was conducted from January 2016 to January 2020 at a tertiary care centre in Northeast India. We reviewed the medical records and collected data on patients with ERCP induced perforations. We analysed the type of injury, management and outcomes. **Results:** A total of 450 ERCPs were performed at our centre during the study period. Eleven patients (2.4%) developed ERCP related perforations. Two patients had type I injury, identified during ERCP and managed by urgent surgery. Three patients with type II injury were managed conservatively. One patient with type III injury was detected intra-operatively on laparoscopy for planned laparoscopic cholecystectomy, which was organised by placing subhepatic and pelvic drains. Five patients with type IV injury were also managed conservatively. **Conclusion:** Type I injuries require immediate surgical or endoscopic closure whenever possible. An initial conservative approach to small perforation for type II injury may be appropriate, but surgical consultation and careful observation is mandatory. Type III and IV injuries almost always improve after conservative treatment.

**Keywords:** Endoscopy; perforation; emergency surgery; hepato-pancreaticobiliary diseases.

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### INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a widely used diagnostic and therapeutic tool in hepatopancreaticobiliary diseases. Though considered safe, it is associated with certain significant complications like

pancreatitis, cholangitis, perforation and bleeding. ERCP-related perforations are a rare but severe complication of ERCP with high morbidity and mortality rates. The incidence of ERCP-related perforation ranges from 0.3% to 1.3%.<sup>1-7</sup> The mortality rate in perforated patients has been reported to be as high as 25%.<sup>8</sup>



It is generally agreed that some ERCP-related perforations can be successfully managed without surgery;<sup>6,9</sup> however, it is difficult to define these patients. Further, once a plan of non-operative management is made, these patients should be under constant surveillance by a surgical team so that the patient may be immediately operated on if deterioration occurs. Data on the management of these ERCP related perforations in resource-constrained settings like ours is sparse. We, therefore, decided to review our experience with the management of ERCP related perforations.

**Patients and methods:** This was a retrospective study. We reviewed the records from January 2016 to January 2020 of our endoscopy department to assess the number of ERCPs performed. From these records, patients admitted with ERCP related perforations were identified. The patients' medical records with ERCP related perforations were reviewed retrospectively, and data was collected regarding their presentation, management, and outcomes. ERCP-related perforations were classified according to Howard and Stapfer's classification (**Table 1**).<sup>10-11</sup>

**Table 1** Classification systems of endoscopic retrograde cholangiopancreatography-related perforations

Type of injury	Stapfer et al. <sup>11</sup>	Howard et al. <sup>10</sup>
Type I	Lateral or medial wall perforation	Guidewire perforation
Type II	Peri-Vaterian injury	Periampullary retroperitoneal perforation
Type III	Distal bile duct injury related to wire/basket instrumentation	Guidewire perforation
Type IV	Retroperitoneal air alone	None

## RESULTS

450 ERCPs were done at our tertiary referral centre in Guwahati, Assam, India, between January 2016 and January 2020, and we identified and managed 11 (2.4%) perforations. Two of these patients with ERCP-related injury were referred to our hospital for management. These two patients were also included in this study. Eight were female among these 11 patients, and three were male with a median age of 52 years (31-72 years). Fluoroscopy during ERCP, abdomen and chest X-rays and Contrast-Enhanced Computed Tomography (CECT) abdomen were used to diagnose the underlying conditions. All these patients indicated common bile duct stone, with or without biliary stricture and associated cholangitis. The most typical type of injury was a type IV injury in 45.45% of patients. Most patients were managed conservatively (82.82%). Details of individual

patients are presented below according to Stapfer's type of perforation (**Table 2**).

**Table 2** Patients' details

Patient characteristics		Observations
Age	Range (Median)	31-72 years (52 Years)
Sex	Male:Female	3:8
Stapfer's type of injury	Type I	2 (18.18%)
	Type II	3 (27.27%)
	Type III	1 (0.91%)
	Type IV	5 (45.45%)
Management	Surgery	2 (18.18%)
	Conservative	9 (81.82%)
Post ERCP stay	Type I	9 days
	Type II	9 Days
	Type III	5 Days
	Type IV	7 Days

### Type I injury

Two patients had type I injury. The indication for ERCP in both these patients was multiple CBD calculi. Both these cases were identified during the procedure of ERCP itself and were managed by urgent surgery in the same sitting. Both patients had a lateral wall injury in the second part of the duodenum, and they were managed by primary repair. After Kocherisation of the duodenum to obtain control, the perforation was closed transversely in two layers with interrupted sutures with inner 4-o polydioxanone and outer 3-o silk.

Additionally, retro colic -isoperistaltic gastrojejunostomy was added to divert the gastric juice. Cholecystectomy and CBD exploration were also done to remove the calculi, and the CBD was closed over a T-tube to divert the bile. The nasogastric tube was removed on a post-operative day (POD)3, a liquid diet was started, and a T-tube was clamped on POD4. The subhepatic drain was removed on POD8, and patients were discharged the next day with clamped T-tube in-situ, which was subsequently removed on POD21 after a good T-tube cholangiogram.

### Type II injury

Three patients had type III perforation. These were not picked up intra-procedure but diagnosed later when they complained of abdominal pain and discomfort post-procedure. These patients were kept under observation. The patients failed to improve over the next 24 hours and developed tachycardia and mild abdominal distention, tenderness and absent bowel sounds. Urgent CECT was done, revealing minimal retro-duodenal and right perinephric collections in

all patients. Because of the absence of free air and apparent peritonitis, they were planned for conservative management with nil orally, intravenous fluids, indwelling nasogastric tube and injectable antibiotics and analgesics. Patients improved clinically on medical management. Repeat CECT was done on day 3 of the procedure and revealed a significant decrease in the size of the collections. Hence, conservative treatment was continued. Two of the patients improved with this management and were started on orals on day 8. However, one patient developed pain abdomen and underwent repeat CECT on day 6, which did not show any collection and conservative treatment was continued. On day 8, the nasogastric tube was removed, and a liquid diet was started. Patients were discharged on the following day after they tolerated a regular diet.

### **Type III injury**

One patient had a type III injury. This was diagnosed intra-operatively during laparoscopy for planned cholecystectomy on post-procedure day 1. On laparoscopy, bile was detected in subhepatic and pelvic regions. Since the patient was asymptomatic, it was decided to manage him conservatively by placing right subhepatic and pelvic drains. CECT was done but did not reveal any leak. Drain output was 30 ml in subhepatic and 40 ml in the pelvic drain in the first 24 hours, bile stained serous fluid. The output was gradually reduced, turned to severe, and drains removed on the 5<sup>th</sup> day of the procedure. The patient was discharged with the plan for laparoscopic cholecystectomy and CBD stent removal after four weeks. He underwent a successful cholecystectomy later on.

### **Type IV injury**

Five patients had type IV injuries and were also managed conservatively. All these patients underwent successful CBD clearance and stent placement. However, patients developed abdominal pain post-procedure, and mild enlargement and tenderness were detected on examination. Urgent CECT was done, which revealed retroduodenal air in all these patients. In addition, three patients had associated right perinephric air, two patients had associated pneumomediastinum, and one patient had associated subcutaneous emphysema in the right upper trunk. All patients improved with medical treatment and were discharged within seven days.

## **DISCUSSION**

ERCP-related bowel perforations are infrequent but potentially lethal complications, with an unpredictable outcome. Predisposing factors that increase the risk of ERCP-related perforation include sphincter of Oddi dysfunction, older age, undilated bile duct, sphincterotomy, and longer procedure duration.<sup>2</sup> Other reported risk factors are abnormal

duodenal anatomy and peripapillary duodenal diverticulum.<sup>7</sup>

Though the appropriate management of ERCP-related perforations has been controversial, increasing experience with evidence suggests that most ERCP-related perforations can be managed without surgery.<sup>6,9</sup> Stapfer's classification helps classify the perforations following the mechanism and location. Exceptions include typing I injuries, which are scope induced and require urgent intervention, either with endoscopic clipping, suturing, or surgical repair. Type II injuries can often be managed conservatively but may require exploration on failure to improve. It is also important to note that these perforations may be associated with pancreatitis, which increases the risk of mortality and morbidity. If identified during the procedure, stenting may be performed. They require close observation and early intervention. Type III and Type IV are usually managed conservatively and often missed as most patients may be asymptomatic.<sup>12</sup>

Our data shows that nearly 80% of ERCP related perforations can be managed conservatively. This is in concordance with what other authors have reported as well.<sup>13</sup> However, it is essential to involve a surgical team from the beginning to allow a surgical intervention to be performed at the earliest sign of deterioration.

The main drawback of our study is that it is a tiny sample, and ERCP-related perforation is a rare complication by itself. Further, this study details the management of these patients at a tertiary care centre from North East India.

## **CONCLUSION**

All type I injury require immediate surgical or endoscopic closure whenever possible. Though a conservative approach can manage type II injury, surgical consultation and careful observation are mandatory. Type III and IV injuries almost always improve with conservative treatment.

**Data availability:** The data used to support the findings of this study are included in the article.

**Conflicts of interest:** None declared.

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### RESEARCH PAPER

# Prevalence of hyponatremia in Cirrhosis and its correlation with severity of the disease

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**Background and aims:** Clinical manifestations of cirrhosis result from pathophysiological changes and also reflect the severity of the disease regardless the etiology. Portal hypertension is a major complication of cirrhosis which leads to development of ascites and esophageal varices.<sup>1</sup> **Method:** 232 cirrhotic patients were included in this study from November 2017 to December 2018. Hyponatremia was defined as serum sodium level <135mEq/L and was classified as severe, moderate and mild. Disease severity was described using Child-Pugh Score (CPS) and Model for End-Stage Liver Disease (MELD) score. Association between categorical variables were tested using the Chi-square test. Correlation between variables was assessed using the Pearson correlation coefficient. Statistical analysis was performed with IBM SPSS Statistics version 21 Software. A p-value less than or equal to 0.05 was considered significant. **Results:** Out of 232 patients 33.62% (n=78) had normal sodium levels while 154 patients had hyponatremia among whom 19% (n=46), 15.52%, (n=36), 31.62 % (n=72) patients had severe, moderate and mild hyponatremia respectively. Sodium level was negatively correlated (r= -0.254) with MELD score (p <0.0). The majority of the patients had hyponatremia in CPS class C, followed by Class B and Class A in different hyponatremia groups. **Conclusion:** Hyponatremia is a prevalent finding in Cirrhosis of the liver, especially in an advanced stage. The severity of hyponatremia correlates with the severity of liver disease and complications in the majority of the cases.

**Keywords:** Cirrhosis, Hyponatremia, Disease severity, Child-Pugh Score, MELD Score

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## INTRODUCTION

Cirrhosis of the liver is defined by diffuse hepatic fibrosis, where regenerative and degenerative nodules replace the typical architecture of the liver.<sup>1</sup> Clinical manifestations of cirrhosis result from pathophysiological changes and also reflect the severity of the disease regardless the etiology. Portal hypertension is a major complication of cirrhosis which leads to development of ascites and esophageal varices.<sup>1</sup> Variceal bleeding, ascites, encephalopathy, jaundice, SBP, hepatorenal syndrome (HRS), coagulopathy, and hepatocellular carcinoma are the complications in decompensated Cirrhosis, some of which are life-threatening. Electrolyte imbalances like hyponatremia and hypokalemia are frequent manifestations of decompensated Cirrhosis.

In hospitalized patients, hyponatremia is a widespread manifestation, occurs in up to 22% of the cases.<sup>2</sup> Hyponatremia is generally defined as a serum sodium level < 135mEq/l. While in the case of cirrhotic patients, serum sodium < 130 mEq/l is considered hyponatremia and is found in up to 20-30% of the cases.<sup>2-4</sup> Hyponatremia in cirrhotic patients are usually asymptomatic, but in some cases, it may develop nausea, vomiting, anorexia, lethargy and rarely seizure.

Hyponatremia in Cirrhosis may be due to hypovolemia or, more commonly, hypervolemia. Hypovolemic hyponatremia, representing 10% of all patients with Cirrhosis of the liver,<sup>5</sup> results from a substantial loss of extracellular fluid over sodium, either from the kidney due to high diuretics or high diuretics the gastrointestinal tract due to diarrhoea or vomiting.

Hyponatremia in cirrhotic patients is hypervolemic or dilutional hyponatremia.<sup>6</sup> Pathogenesis of hyponatremia in Cirrhosis is nonosmotic hypersecretion of arginin vasopressin from neurohypophysis related to circulation dysfunction. It is associated with increased mortality and morbidity from HRS and hepatic encephalopathy. It is also connected with the increased likelihood of complications in hepatic transplantation in the form of reduced short time survival.

Hyponatremia occurs due to impaired circulatory volume, primarily due to peripheral vasodilatation, leading to secretion of AVD and reduction in renal perfusion and GFR(glomerular filtration rate). Ultimately, there is impaired free water clearance.<sup>7</sup>

Hyponatremia in cirrhotic patients has been associated with a reduction in myoinositol, a brain organic osmolyte, which may play an essential role in the genesis of hepatic encephalopathy.<sup>6</sup> The mainstay of managing hyponatremia is fluid restriction and salt restriction, potassium correction and the use of diuretics. Intravenous albumin infusion may be effective for a short duration.<sup>8</sup>

Hyponatremia is a predictor of reduced survival in cirrhotic patients with ascites (9,10) regardless of the aetiology and a significant risk factor for life-threatening complications like HRS and hepatic encephalopathy. (4,5) So, early detection and proper management are essential in treatment perspectives.

Alcoholic liver disease and Cirrhosis are widespread due to high alcohol intake in this part of the country. However, the prevalence of hyponatremia in cirrhotic patients has not been studied widely. Therefore the present study has investigated the prevalence of hyponatremia in cirrhotic patients and its correlation with the severity of the disease and its complications.

## MATERIAL AND METHODS

It was a cross-sectional hospital-based observational study conducted in our hospital. According to the study criteria, 232 randomly selected cirrhotic patients were included from November 2017 to December 2018.

All patients with Cirrhosis were included. If available, the diagnosis of Cirrhosis of the liver was made by clinical examination, laboratory investigations, USG and histopathological report. Cirrhotic patients with heart failure, chronic kidney diseases, hepatocellular malignancy and drugs therapy (SSRI, TCA, MAO inhibitors) were excluded from the study. Patients were examined clinically and by laboratory investigations, including complete blood count, urine analysis, renal function test, serum sodium and potassium, liver function tests, blood glucose, prothrombin time(PT), INR, ultrasound abdomen, UGI endoscopy, chest x-ray and

ascitic fluid analysis, wherever indicated. Informed consent was taken from the patients.

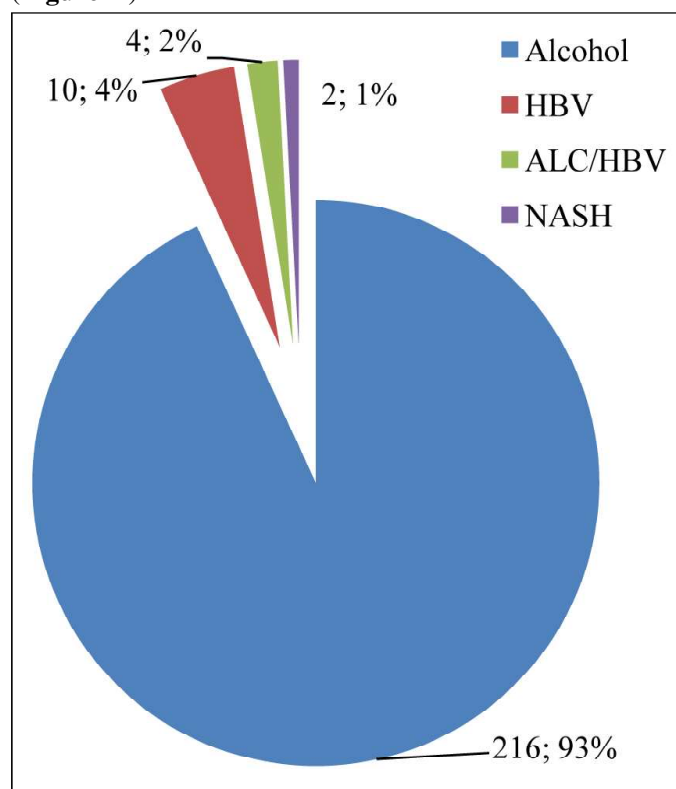
Hyponatremia was defined as serum sodium level  $< 135\text{mEq/l}$  and was subdivided into three different groups like severe ( $< 125\text{mEq/l}$ ) A serum sodium level  $> 136\text{mEq/l}$  is considered normal.. A serum sodium level  $> 136\text{mEq/l}$  is considered normal. CPS (class A, B and C) and MELD scores describe disease severity. The MELD score was divided into subgroups like  $< 10$ , 11-20, 21-30 and 31-40.

## Statistical analysis

Pearson's chi-square test was used to test any association between categorical variables. To assess the correlation between variables, the Pearson correlation coefficient was used. Statistical analysis was performed with IBM SPSS Statistics version 21 Software. A p-value less than or equal to 0.05 was considered significant.

## RESULTS

A total of 232 patients were included in this study, among whom the majority were alcoholic Cirrhosis (93.10%), followed by HBV infection and alcohol plus HBV infection (Figure 1).



**Figure 1** Aetiology

Out of 232 patients, 209 were male, and 23 were female. The age range of the patients was 28 to 78 years with a mean ( $\pm$ S.D.) age of  $47.34(\pm 10.26)$  years. The most common presenting features of Cirrhosis were ascites

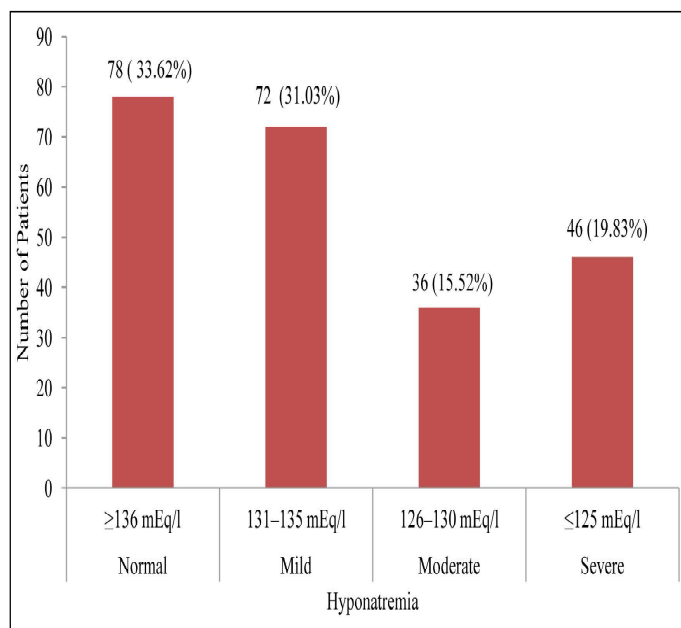


(78.45%), jaundice (50.86%) and pain abdomen (43.97%). Hepatic encephalopathy (24.14%), UGI bleeding (20.6%), tense ascites (18.10%), SBP (16.81%) and hepatorenal syndrome (10.34%) were also observed in few cases (Table 1).

**Table 1** Basic Characteristics of Cirrhotic patients (n = 232)

Characteristics	Mean $\pm$ S.D	Range
Age (in years)	47.34 $\pm$ 10.26	28–78
Sex:	Number (n)	Percentage (%)
Male	209	90.09
Female	23	9.91
Presenting Features	Number (n)	Percentage (%)
Ascites/ Distension of Abdomen	182	78.45
Jaundice	118	50.86
Pain Abdomen	102	43.97
Bacterial Infection	84	36.21
Fever	80	34.48
Hepatic Encephalopathy	56	24.14
UGI Bleeding	48	20.69
Tense Ascites	42	18.10
SBP	39	16.81
Hepatorenal Syndrome	24	10.34

Out of 232 patients, 33.62% (n=78) had normal sodium level. The overall prevalence of hyponatremia was 66.38%, with 19.83% of patients having mild, 15.52% having moderate and 31.03% having severe hyponatremia (Fig. 2).



**Figure 2** Prevalence of Hyponatremia among patients with Cirrhosis

The mean ( $\pm$ S.D.) MELD score of the patients was 24.16 ( $\pm$  7.78). Serum sodium level (mEq/l) was found to be negatively correlated ( $r=-0.254$ ) with MELD score ( $p<0.001$ ), suggesting that patients with lower sodium levels had more severe disease (Table 2).

**Table 2** Correlation between MELD score and the sodium levels

Sodium (mEq/l)	MELD Score (Mean $\pm$ S.D)	<i>r</i> value	<i>p</i> value
$\geq 136$	21.59 $\pm$ 8.15	-.254	<0.001
131–135	23.31 $\pm$ 6.51		
126–130	24.33 $\pm$ 7.29		
$\leq 125$	29.70 $\pm$ 6.70		
Overall	24.16 $\pm$ 7.78		

Based on the MELD score, patients were assigned to 4 groups, <10, 11–20, 21–30 and 31–40. These scores indicated that as hyponatremia became more severe, the MELD score increased, suggesting an association of declined liver function with a degree of hyponatremia (Table 3).

**Table 3** MELD Score

MELD Score	Sodium (mEq/l)				Total (n = 232)	<i>p</i> value
	$\leq 125$ (n = 46)	126–130 (n = 36)	131–135 (n = 72)	$\geq 136$ (n = 78)		
$\leq 10$	0	0	0	6 (7.69%)	6 (2.59%)	0.007*
11–20	2 (4.35%)	12 (33.33%)	18 (25.00%)	28 (35.90%)	60 (25.86%)	0.001*
21–30	28 (60.87%)	18 (50.00%)	42 (58.33%)	34 (43.59%)	122 (52.59%)	0.183
31–40	16 (34.78%)	6 (16.67%)	12 (16.67%)	10 (12.82%)	44 (18.97%)	0.021*

In this study, most of the patients (60%) had a CPS score of C followed by CPS score B (32.76%), and only 6.9% of the patients had a CPS score A. In every range of hyponatremia, the majority of the patients had CPS class C followed by Class B and Class A. These scores indicate that as hyponatremia became more severe, liver function declined (Table 4).

**Table 4** Child-Pugh Score

Child-Pugh	Sodium (mEq/l)				Total (n = 232)	<i>p</i> value
	$\leq 125$ (n = 46)	126–130 (n = 36)	131–135 (n = 72)	$\geq 136$ (n = 78)		
A (5–6)	0	2 (5.56%)	2 (2.78%)	12 (15.39%)	16 (6.90%)	0.003*
B (7–9)	6 (13.04%)	10 (27.78%)	24 (33.33%)	36 (46.15%)	76 (32.76%)	0.002*
C (10–15)	40 (86.96%)	24 (66.67%)	46 (63.89%)	30 (38.46%)	140 (60.35%)	0.000*

The chi-square test revealed significant associations of the number of patients having various complications of Cirrhosis with the severity of hyponatremia. As seen from Table 3, hepatic encephalopathy and HRS, two significant complications of Cirrhosis, were significantly associated with severe hyponatremia ( $p$ -value<0.05). Out of 56 patients with hepatic encephalopathy, 20 (43.48%) had a serum

Sodium level <125mEq/l, while among the 24 patients with Hepatorenal syndrome, 20 had severe hyponatremia. Except for bacterial infections and UGI bleeding, the occurrence of other complications like ascites, Tense Ascites and SBP were also found to be significantly associated with the degree of hyponatremia (p-value<0.05). While ascites and UGI bleeding were found to occur among patients with any level of hyponatremia, the other complications were found to occur more among patients with serum sodium Level <125mEq/l. It was observed that patients with a Serum sodium concentration <135mEq/l had a significantly increased risk of developing complications than Patients with serum sodium >136mEq/l. Among patients with hyponatremia, the risk of developing complications was higher among those with severe hyponatremia than moderate and mild hyponatremia cases (Table 5).

**Table 5** Frequency of complications of Cirrhosis in different serum sodium level groups

	Sodium (mEq/L)			Normal ≥136(mEq/ L) (n = 78)	p- Value
	≤125 (n = 46)	126–130 (n = 36)	131–135 (n = 72)		
Ascites (182)	26 (56.52%)	30 (83.33%)	60 (83.33%)	66 (84.62%)	0.001*
Bacterial Infection (84)	24 (52.17%)	12 (33.33%)	22 (30.56%)	26 (33.33%)	0.090
Hepatic Encephalopathy (56)	20 (43.48%)	8 (22.22%)	14 (19.44%)	14 (17.95%)	0.007*
Hepatorenal Syndrome (24)	20 (43.48%)	2 (5.56%)	0 (0.00%)	2 (2.56%)	<0.001*
Tense Ascites (42)	18 (39.13%)	6 (16.67%)	8 (11.11%)	10 (12.82%)	0.001*
SBP (39)	14 (30.43%)	9 (25.00%)	8 (11.11%)	8 (10.26%)	0.008*
UGI Bleeding (48)	8 (17.39%)	10 (27.78%)	18 (25.00%)	12 (15.38%)	0.313

## DISCUSSION

Cirrhosis of the liver is very common due to the high prevalence of alcohol intake in this part of the country. In the advanced stage of liver disease, along with other complications, hyponatremia is also a widespread manifestation associated with increased mortality.

In the present study, the overall prevalence of hyponatremia was 66.38%. Out of 232 patients, 78 patients (33.62%) had average serum sodium level, whereas 72 patients (31.03%), 36 patients (15.52%), and 46 patients (19.83%) had mild, moderate and severe hyponatremia, respectively. The findings are concordant with similar other studies.<sup>7,11-15</sup> However, in the present study, the prevalence of

hyponatremia was a little higher due to the enrolment of patients irrespective of diuretics therapy.

In the present study, we have observed that hyponatremia more commonly occurs with CPS class C (60.34%) followed by CPS B (32.76%) and a high MELD score (mean 24.16 +/-7.78). The correlation between serum sodium concentrations and MELD score had shown a strong negative correlation with a correlation coefficient -0.254 (p-value <0.001). This finding was similar to another study.<sup>11</sup>

Of 232 patients, 60.35% had CPS class C followed by 32.76% and 6.90% patients in class B and class A, respectively. Out of 46 patients with severe hyponatremia, the majority, 40 patients (86.96%), were in CPS class C. Similarly, 24 out of 36 patients (66.67%) with moderate hyponatremia, 46 out of 72 patients (63.89%) with mild hyponatremia and 30 out of 78 patients (38.46%) with average sodium level were in class C of CPS. The association between CPS classes and serum sodium concentration was statistically significant (p-value<0.05). This finding was in agreement with various studies suggesting a significant correlation between the disease severity and hyponatremia.<sup>11,16</sup>

The association between the severity of hyponatremia and complications were also assessed in this study. Except for ascites and upper GI bleeding, it was observed that as the severity of the hyponatremia increases, the different complications increases. The proportions of patients with hepatic encephalopathy and HRS were significantly higher among patients with severe hyponatremia. Frequency of hepatic encephalopathy, hepatorenal syndrome, SBP, tense ascites was familiar with serum sodium<130mEq/l and specifically among those with Serum sodium level <125mEq/l. Other complications like bacterial infections, tense ascites. Spontaneous bacterial peritonitis(SBP) was more prevalent among patients with severe hyponatremia. Only ascites and upper GI bleeding affected patients with hyponatremia and those with average sodium levels. This finding agrees with similar other studies.<sup>15,16</sup>

Majority of the complications are believed to occur due to increased body fluid resulting from the impairment of solute free water excretion. Hyponatremia plays an essential role in the occurrence of hepatic encephalopathy. The extracellular fluid hypotonicity due to hyponatremia favours the osmotic effects of glutamine and cell swelling and cerebral oedema induced by increased ammonia levels. Moreover, hyperammonemia and hyponatremia alter the myo-inositol metabolism in the brain cells. So, hyponatremia accelerates the neurological effect of altered ammonia metabolism in Cirrhosis.<sup>15,17</sup>

**Limitation:** The current study is a single centred cross-sectional study. Patients were not being followed up.

## CONCLUSION

The present study shows that hyponatremia is a prevalent finding in Cirrhosis of the liver, especially in an advanced stage. Hyponatremia in Cirrhosis is usually associated with various complications. The severity of hyponatremia correlates with the severity of liver disease and difficulties in the majority of the cases.

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### RESEARCH PAPER

# A clinico-epidemiological study of acute encephalitis syndrome in a tertiary care hospital of Assam, India

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**Background and aims:** India's significant public health problem is Acute encephalitis syndrome (AES). The present study aims to assess the clinico-epidemiological profile of acute encephalitis syndrome in a tertiary care hospital of Assam, India. **Methods:** A single centre prospective observational study was conducted on AES patients admitted to the Department of Medicine in Tezpur Medical College and Hospital, Assam, India. Clinical features, disease outcome, CSF, biochemical and radiological profiles were studied. All cases above 12 years that fulfil the WHO case definition of AES were included. Informed/written consent was obtained before data collection. Prior Ethical clearance was obtained from the Institutional Ethics Committee. Chi-square and Student's t-test was used to determine significance. Statistical analysis was carried out using Statistical Package for the Social Sciences (SPSS) version 20. The p-value < 0.05 is considered significant. **Results:** Majority (67%) of the cases were male and belonged to the age group 30-40 years. A total of 126 patients (58%) tested positive for Japanese Encephalitis (JE). Fever (97%) and altered sensorium (90%) are the main clinical presentation. Most cases were reported from May to July ( $P < 0.05$ ). Out of 218 AES cases, 69 patients (33%) expired, 104 (47%) were recovered entirely, and 29 (13%) had neurological sequelae. **Conclusion:** JE is still the primary cause of AES in this country. Early diagnosis, treatment and vaccination might help effective management and prevention of the disease.

**Keywords:** Acute Encephalitis syndrome, Japanese Encephalitis, Tezpur, Assam

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### INTRODUCTION

Acute encephalitis syndrome is considered a significant public health problem in India due to the increased morbidity and mortality associated with the disease.<sup>1</sup> As per the World Health Organisation (WHO), the clinical case definition of AES is a person of any age at any time of year with the acute onset of fever and a change in mental statuses such as confusion, disorientation, coma, or inability to talk and new onset of seizures (except simple febrile seizure).<sup>2</sup> An

increase in irritability, somnolence, or abnormal behaviour greater than that seen with usual febrile illness are AES's other early clinical findings.<sup>3</sup> The disease most commonly affects children and young adults, although the entire spectrum of age groups can be involved.<sup>1</sup> The average incidence is between 3.5 and 7.4/100,000 patient-years, the incidence being higher in children.<sup>4,5</sup>

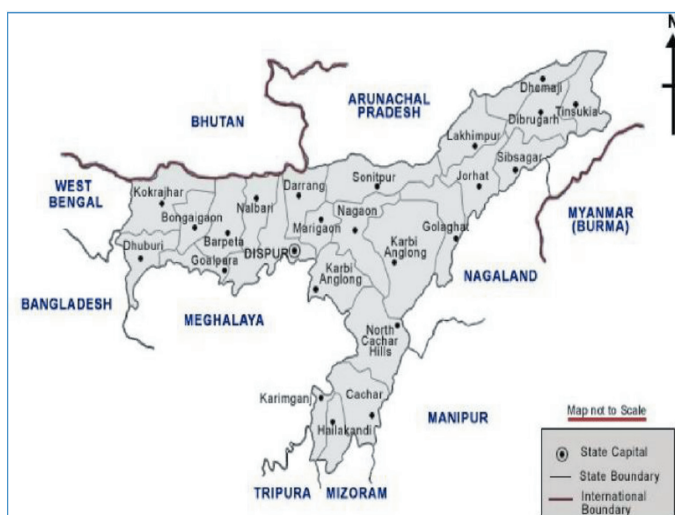
Viruses are the main causative agents in AES cases. However, other sources such as bacteria, fungus, parasites,



spirochetes, chemicals, toxins and non-infectious agents have also been reported over the past few decades.<sup>6</sup> Broadly, they can be classified into infective and non-infective agents. Although viruses are the primary cause of AES, aetiology remains unidentified in many cases.<sup>4</sup> The causative agent of AES varies with season and geographical location and predominantly affects populations below 15 years.<sup>5</sup> The type of viruses also markedly differs in different parts of the world. In China, the UK, Norway, Spain, and France, HSV is a common viral agent for AES.<sup>7-11</sup> Whereas Japanese encephalitis virus (JEV) is the primary cause of AES in India (ranging from 5%-35%).<sup>12,13</sup> Herpes simplex virus, Influenza A virus, West Nile virus, Chandipura virus, mumps, measles, dengue, Parvovirus B4, enteroviruses, Epstein-Barr virus and scrub typhus, *S. pneumoniae* are the other causes of AES in sporadic and outbreak form in India.<sup>14</sup> Nipah and Zika viruses are also causative agents for AES.<sup>1</sup> According to the NVBDCP data, AES cases were reported mainly from Assam, Bihar, Jharkhand, Karnataka, Manipur, Meghalaya, Tripura, Tamil Nadu, and Uttar Pradesh. In India during 2018, 15% of cases of AES were found positive for infection due to JEV.<sup>1</sup>

Although AES cases other than JE continue to be reported throughout the year, there is an overall increase of total AES cases since June, peak during July- August and decline in September-October. All the endemic States except Assam start reporting JE cases from July onwards and attain a peak in September-October. In Assam, the cases start appearing from February, and the peak is in July.<sup>3,15</sup> With a high case fatality rate and frequent residual neuropsychiatric damage in survivors, JE is a significant public health problem. Almost 50,000 cases and 10,000 deaths are reported each year, primarily amongst children.<sup>15</sup>

To study the clinico-epidemiological profile of acute encephalitis syndrome in a tertiary care hospital of Assam, India.



## MATERIALS AND METHODS

A single centre prospective observational study was conducted on patients admitted to Tezpur Medical College and Hospital, Assam, India. Clinical features, disease outcome, CSF, biochemical and radiological profiles were studied in AES cases. All cases aged over 12 years, admitted to the Department of Medicine, Tezpur Medical College, who fulfil the WHO case definition of AES, were included in the study.

Based on the case definition, 218 cases were enrolled for the study. Informed consent was obtained from the parents or legal guardians of the participants. Ethical clearance for the study was obtained from the Institutional Ethics Committee. Data on demographic and clinical observations were recorded in a predesigned questionnaire. Case reporting was done in standard Case Investigation Form for clinical and demographic characteristics documentation and Laboratory Request Form as per guidelines set by National Vector Borne Disease Control Programme (NVBDCP), Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.

All cases satisfying the WHO clinical definition of AES were subjected to Routine blood investigations and NCCT Brain in Emergency Department. After admission in the Medicine ward, lumbar puncture was performed under all aseptic and antiseptic precautions, and CSF (2 ml) was collected. In addition, a serum sample was obtained at the same time. Both serum and CSF samples were kept at 4-8°C if testing is done within 48 h, for short- and long-term storage kept in a deep freezer at -20° and -80°C, respectively. Cerebrospinal fluid (CSF) was analyzed for physical, biochemical, cytological, ADA, HSV, IgM antibodies to JEV (Mac Elisa technique), HSV and West Nile Virus. Testing for scrub typhus (IgM) and *Leptospira* (ELISA) was done in highly suspicious cases. Serum was analyzed for IgM antibodies to JEV, Dengue (NS1 for symptoms less than 5days, IgM antibodies for signs more than 5 days), *Orientia tsutsugamushi* (causative agent for Scrub typhus) and Chikungunya. The viral aetiology of Encephalitis was considered either definitive or possible based on the sample type and evidence of viral infection. The presence of viral genome by PCR/RT-PCR / culture of virus or detection of IgM antibodies in CSF was considered “definitive”.

In contrast, the presence of viral genome by PCR/RT-PCR from blood samples or detection of IgM antibodies in serum and absence of above viral markers in CSF was considered “possible”. JE Samples were reported as positive or negative, or equivocal. A second serum sample from the patient was obtained 10-14 days after the first sample in the uncertain result. Selected patients were also taken for MRI Brain to



look for active lesions and residual deficits during follow up.

**Statistical analysis:** The data were statistically analyzed using the Chi-square test for categorical variables and the t-test for continuous variables to determine significance. Data were analyzed using Statistical Package for the Social Sciences (SPSS) version 20. A *p-value* <0.05 is considered significant.

RESULTS

Out of 218 cases taken up for the study, male preponderance with 67% cases was recorded. The highest number of patients (26%) belongs to 30-40 years (**Table 1**). Out of 146 males, 102 (70%) were found to be JE +ve, and 44 (30%) were Non-JE cases, while in the case of females, 24(33 %) were found to be JE +ve, and 48 (67%) were Non-JE cases.

Table 1 Age and gender distribution of AES cases

Age group(years)	Number	Percentage
12-20	39	18
20-30	42	19
30-40	57	26
40-50	34	16
50-60	21	9
>60	25	12
Sex		
Male	146	67%
Female	72	33%

**Clinical profile:** Most cases presented with fever (97%) and altered sensorium (90%) followed by headache, neck rigidity, vomiting and seizures. Cranial nerve involvement was seen in rare cases, primarily involving third and seventh cranial nerves with 4% of patients (**Table 2**).

Table 2 Clinical features of study participants

CLINICAL FEATURES	NUMBER(n)	PERCENTAGE (%)
Fever	212	97
Altered Mental Status	198	90
Headache	166	76
Vomiting	70	32
Seizures	34	15
Neck Rigidity	113	51
Paralysis	20	9
Cranial nerve injury	10	4

**Etiological profile:** Of 218 cases included in the study, 126 patients (58%) tested positive for JE. The test was confirmed with IgM antibodies to JEV in CSF or serum.

A significant proportion (14%) was also found to be TBM +ve, confirmed by a rise in CSF ADA level and radiologic changes (**Figure 1**).

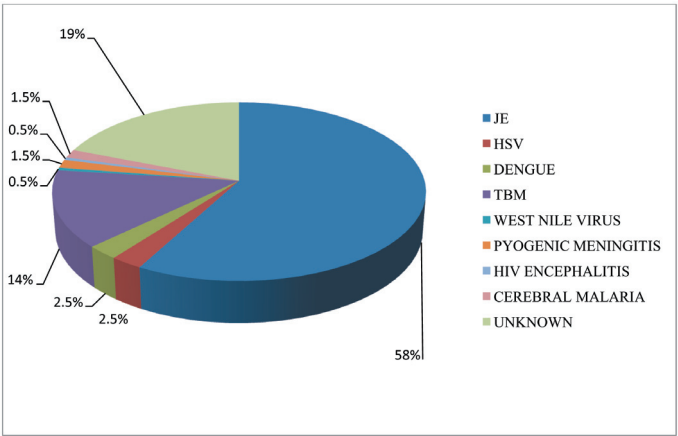


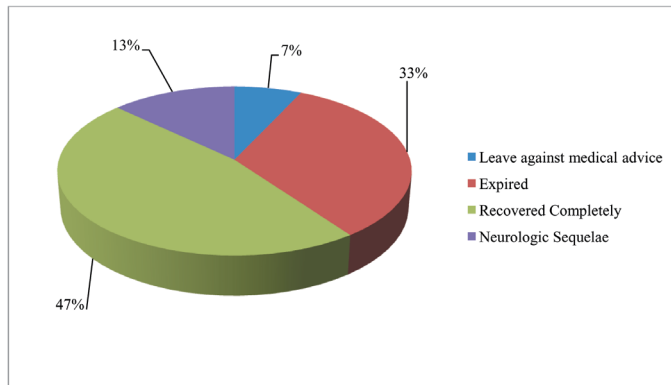
Figure 1 Etiological Profile of AES cases

**Seasonal variation and socio-demographic profile:** The majority of the cases (77.1%) were reported from May to August, and the association were found to be statistically significant (P <0.05) among viral and non-viral AES cases. Most AES cases were reported from rural areas (76.2%). The association between socioeconomic status and the living condition with viral and non-viral AES cases was found to be statistically insignificant (**Table 3**).

Table 3 Socio-demographic and temporal profile among viral and non-viral AES cases

Socio-demographic and temporal variable	Viral AES (n=138)	Non-Viral AES (n=80)	p-value for $\chi^2$
<b>Economic Condition</b>			
Upper	38 (27.5%)	21 (26.2%)	0.96
Middle	53 (38.4%)	32 (40.0%)	
Lower	47 (34.0%)	27 (33.7%)	
<b>Residential Status</b>			
Rural	76 (55.1%)	46 (57.5%)	0.73
Urban	62 (44.9%)	34 (42.5%)	
<b>Season</b>			
January-April	32 (23.2%)	25 (31.3%)	0.02
May-August	77 (55.8%)	29 (36.2%)	
September-December	29 (21.0%)	26 (32.5%)	

**Outcome:** The clinical outcome was reported for 202 patients. The status of 16 patients (7%) could not be ascertained as the patients leave against medical advice. A total of 69 patients (33%) expired, 104 (47%) were recovered entirely, and 29(13%) had neurological sequelae, which were further evidenced by specific MRI findings (**Figure 2**).



**Figure 2** Clinical Outcome of AES cases

**Laboratory profile:** Out of the 218 AES cases, 138 (63.3%) were confirmed for viral AES. The laboratory profiles of viral and non-viral AES cases are presented in **Table 4**. Significant differences in mean levels of various laboratory parameters were observed among viral and non-viral patients. The lower mean level of total leucocyte count, platelet count and CSF protein was observed in viral AES cases with a p-value <0.05.

**Table 4** Laboratory profile of viral and non-viral AES cases

Parameters	Viral AES (mean ±sd)	Non- viral AES (mean ±sd)	P-value for t-test
Hemoglobin(g/dl)	11±3.2	10±2.3	0.015
Total leucocyte count (cumm)	12.9±3.8	13.9±2.8	0.041
Platelet (lakh/cumm)	1.4±0.8	1.6±0.9	0.092
Totalserum bilirubin (mg/dl)	0.8±0.5	1.0±0.8	0.024
Serum Albumin (g/L)	4.0±0.7	3.5±1.2	<0.001
AST(U/L)	66±15	54±5	<0.001
ALT(U/L)	54±23	45±17	0.003
CSF–cell count (cumm)	86±25.8	79±23.2	0.047
CSF–Sugar (mg/dl)	50±12.6	40±23.7	<0.001
CSF –Protein (mg/dl)	98±13.8	117±22.4	<0.001

## DISCUSSION

In our clinical study conducted in a tertiary care hospital of Assam, male preponderance was observed with the male-female ratio of 2:1. Most of the male cases were caused by JE, while no such predominance was found in females. A significant portion of patients (26%) belonged to the age group 30–40 years, in contrast to other similar studies where the prevalence of old age and paediatric age group was more common.<sup>15–17</sup>

The most common clinical presentation was fever (97%) and altered sensorium (90%), followed by headache, neck rigidity, vomiting and seizures. This finding was similar to other clinical studies.<sup>18,19</sup> Change in mental status has been a predominant symptom in the observation of other authors.

Out of multifactorial cases, JE (58%) is the predominant cause of AES in our study, confirmed by CSF or Serum JE specific IgM antibodies. This finding followed previous studies describing both epidemic and sporadic AES cases in different parts of the world.<sup>20,21</sup> In our study, about 19% of the cases remained undiagnosed, which was also similar to a previous study conducted in north east.<sup>22</sup>

Seasonality of the cases was observed during monsoon season, with the highest incidence of cases reported during May to August, and the results were found to be statistically significant ( $P < 0.05$ ). Although more than half of the patients were reported from rural areas, the effect was statistically insignificant. The comparison between socioeconomic status (upper, middle and lower) and the living conditions (rural or urban) was statistically insignificant. In a similar study conducted in northeast India, the peak of cases was recorded between June to August. A predominant rural distribution was reported.<sup>15</sup> While in another study conducted in Odissa, no significant differences in rural predominance were noted.<sup>16</sup>

In our study, out of a total of 218 patients, 69 (33%) expired, 104 (47%) were recovered entirely, and 29 (13%) had neurological sequelae. In a similar study conducted in North-East, a mortality rate of 24% was reported while 51% were stable and discharged.<sup>22</sup>

## CONCLUSION

In our clinical study, the findings have been most similar to previous studies conducted on similar subjects. Japanese Encephalitis is still the primary cause of AES in this part of the country, and the most common clinical presentation was fever, altered sensorium and headache. Early diagnosis, treatment, and vaccination are critical to the effective management of such cases.

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**Contribution of Authors:** We declared that this work was done by the authors named in this article, and the authors will bear all liabilities about claims relating to the content of this article.

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### RESEARCH PAPER

# A study on clinical application of adipofascial flaps for reconstruction in leg defects

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**Background and aims:** The reconstruction of lower limb defects is challenging, and several options have been applied for soft tissue covers over the years. We evaluate the indications, limitations, advantages and disadvantages of adipofascial flaps in soft tissue reconstruction of leg defects. The paper aims to study the indications, limitations, advantages and disadvantages of adipofascial flaps in reconstructing leg defects. **Methods:** Patients with various soft tissue defects of the leg below the knee were studied retrospectively in 25 patients for 1 year 8 months. Planning for the proposed flap was done depending on the availability of local tissue around the defect. Perforators were located by handheld Doppler for perforated based adipofascial flap. Where a definite perforator was not found, and for small size defects, random pattern adipofascial flaps were planned. The surgery was completed in one surgical time with immediate skin grafting. In all cases, split skin grafting over the flap was used, and the donor sites closed primarily. Flap complications, functional and aesthetic outcomes and their satisfaction with the surgery were assessed. **Results:** There was partial loss of flap in 5 patients. Marginal skin necrosis occurred in 4 patients. Only 2 cases of partial donor skin necrosis required further split skin grafting. The flaps have shown good contour and good donor site scar even in patients with complications. The majority of the cases showed fair to good results on follow up. **Conclusions:** Adipofascial flaps are helpful in the armamentarium of reconstructive surgery, particularly in small to medium-sized lower leg defects and provides aesthetically better recipient-site scar with minimal donor-site morbidity and favourable functional outcome.

**Keywords:** Adipofascial flap, lower leg defect, soft-tissue defect, reconstruction.

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## INTRODUCTION

The reconstructive ladder option for leg defects ranges from simple primary closure to complicated microvascular free tissue transfer. With free tissue transfer, contour defect at the recipient and donor site remains significant. Also, there are limitations in acquiring technical expertise and proper instrumentation, leading to less use of this option. Therefore, local flaps remain a workhorse for coverage of soft-tissue defects of the lower leg.

Adipofascial tissue has evolved from fasciocutaneous flaps.

They are composed of subcutaneous fat and deep fascia with a reliable blood supply. The surgical plane in the leg is deep to the deep fascia.<sup>1</sup> This flap incorporates two plexuses less than fasciocutaneous flaps, i.e., dermal and subdermal plexuses.<sup>2, 3</sup>

The defects around the ankle and foot present a huge problem to plastic surgeons because of lack of local tissue, donor site morbidity and bulkiness following reconstructive surgery.<sup>4,5</sup> Adipofascial flaps are locally available, offer superior donor site scar, single staged and have a wide arc



of rotation up to 180 degrees.<sup>6,7,8,9</sup> The disadvantages include partial /total flap loss, donor site necrosis, marginal skin loss.<sup>10,11,12,13,14</sup>

Therefore, this study was conducted to study the indications, limitations, advantages and disadvantages of adipofascial flaps in reconstructing leg defects.

## MATERIAL AND METHODS

This is a retrospective study carried out from January 2018 to August 2019. Patients of all ages and both sex with clinically small-to-medium-sized post-traumatic/post-surgical defect of the leg requiring flap cover were included in the study. Patients with associated soft tissue contusion around the primary defect, osteomyelitis, large defect with cavity were excluded from the study. Twenty-five patients with leg defects were evaluated and reconstructed with an adipofascial flap cover. Due permission was taken from the institutional research and ethical committee.

The assessment was done based on history, clinical findings, radiological investigations and handheld Doppler study to include a perforator whenever possible. Based on the anatomical location of the defect, adipofascial flap covers were considered after discussing the plan with the patient/attendants. Written/informed consents were taken about the procedure and photographs were taken preoperatively, intraoperatively, postoperatively and on follow-up.

Patients were operated on under regional/general anaesthesia. Planning for the proposed flap was done depending on the availability of local tissue around the defect. Whenever feasible, a perforator-based adipofascial flap was done, but a definite perforator was not located; a random pattern flap was considered. The flaps were either proximally/distally based or vertically based with a transversely oriented flap in a few cases. After planning in reverse, skin flaps were raised as planned just deep to dermis sparing only minimal adipose tissue with the skin flaps and protecting the subdermal plexus. Once adequate skin was undermined, dissection of the adipofascial flap was started from the distal-most part of the flap. A horizontal incision was made through the remaining portion of fat and deep fascia. Then two vertical incisions were made up to the margin of the proposed base. The adipofascial flap was then dissected through the subfascial plane and gently hinged over or transposed to cover the defect. In some of the transposed flaps, the skin was incised at the anterior border of the proposed flap, deepened upto subcutaneous adipose tissue, and dissected until the proposed flap was undermined. For small-sized defects and where a definite perforator was not located, random pattern adipofascial flaps were planned. Those flaps that were turned over were planned considering the defect, the base of the flap, the part of the flap that rolls to allow hinging, the part that rolls over the base and the effective flap that covers the defect. The flap was covered with a

split-thickness skin graft, and the donor area was closed primarily.

Postoperatively, the operated leg was immobilised for one week, and a light dressing was used over the pedicle area. The primary dressing was done on the 5<sup>th</sup> postoperative day. If any, the complications relating to surgery were studied and analysed in all cases. Patients were followed up at 2<sup>nd</sup> week, 4<sup>th</sup> week, 12<sup>th</sup> week and every 6 months till 1.5 years and observations were documented to assess the functional and aesthetic outcome in terms of adequate healing of the wound, any functional limitations imposed by harvesting flap, sensory abnormalities and contour deformities of the donor site.

## RESULTS

Out of 25 patients included in the study, the youngest patient was 4 years, and the oldest was 60 years of age. The mean age was 34.12 years, and the median was 35 years (Table 1).

**Table 1** Number of patients in different age groups

Age group (years)	Number of patients (%)
≤15	5 (20%)
16-30	6 (24%)
31-45	7 (28%)
46-60	6 (24%)
>60	1 (4%)

The majority of the patients were male with a male-female ratio of 4:1 (Table 2)

**Table 2** Gender distribution of patients in different age groups

Age group	Male	Female	Total
≤15 years	1	4	5
>15 years	19	1	20
Total	20	5	25

Traumatic cases constituted major aetiology with 24 defects (96%) and a single non-traumatic case of post-burn unstable scar (4%). The left leg was involved in 16 patients (64%). The location of the soft-tissue defect in the lower limb is shown in Table 3.

**Table 3** Site of involvement

Location of defect	Number of patients (%)
Lower one-third of leg	9 (36%)
Mid-third of leg	7 (28%)
Upper third of leg	1 (4%)
Ankle	3 (12%)
Dorsum of foot	2 (8%)
Tendoachilles region	3 (12%)



Random pattern adipofascial flaps (**Figure 1a, 1b, 1c, 1d** & **Figure 2a, 2b, 2c, 2d**) were used in 14 cases (56%) while perforator based adipofascial flaps (**Figure 3a, 3b** & **3c**) were used in 11 cases (44%). For perforator-based flaps, there were 9 posterior tibial artery perforators and 2 peroneal artery perforator based adipofascial flaps. The adipofascial flap has 2 surfaces, fascial and adipose, either of which can be inserted over the defect. In our study, the adipose side was used for inseting in 15 cases (60%) and in the remaining 10 cases (40%), the fascial side was used. The arc of rotation ranged from 45 degrees to 180 degrees, i.e., for 12 patients (48%), the turnover flap was done in a 180-degree arc of rotation, followed by 90-degree rotation in 11 cases (44%) and a 45-degree rotation in 2 cases (8%).



**Figure 1a** Random adipofascial flap for left lower leg defect



**Figure 1b** Adipofascial flap transposed to defect



**Figure 1c** Immediate postoperative SSG over flap



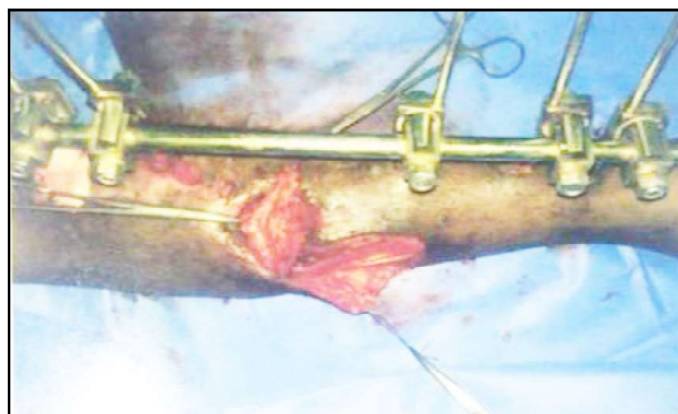
**Figure 1d** 6 months follow-up



**Figure 2a** Right mid-third leg defect



**Figure 2b** Random adipofascial flap raised



**Figure 2c** Flap transposed to defect



**Figure 2d** Immediate post-operative**Figure 2e** Follow-up at 4 weeks**Figure 3a** Right tendoachilles defect**Figure 3b** Flap turned over a defect**Figure 3c** 6 months follow-up

The size of defects ranged from 3x2 cm to 7x5 cm and flaps ranged from 5x3 cm to 12x7 cm. The largest flap (12x7 cm) was a posterior tibial artery perforator-based flap. In 19 cases (76%), flaps were distally based and 4 cases (16%) were proximally based. In 2 cases (8%), the base was vertically based with a transversely designed flap design.

Partial flap necrosis was found in 5 patients (20%) and total flap necrosis in 1 patient (4%). Only 1 case (4%) had partial graft loss, which healed with dressings. Marginal skin necrosis occurred in 4 patients (16%), 2 cases (8%) had partial donor skin necrosis, which required split skin grafting. One case had a hematoma in the donor site, and one hematoma was found above the inset adipofascial flap. There were no cases of flap oedema/venous congestion. There was no hypertrophic scar on follow up. Patients' satisfaction on follow up revealed 8 patients (32%) had excellent result, 11 patients (44%) with good result and 5 patients (20%) with fair result and 1 patient with poor result (4%).

## DISCUSSION

The present study was a retrospective analysis of 25 patients with defects of lower limb requiring soft tissue reconstruction. Out of 25 patients included in the study, 20 were male and 5 were female. The youngest patient was 4 years and the oldest patient was 60 years of age. Similar other studies have also observed wide age range among the patients.<sup>15,16</sup>

Traumatic causes constituted our study's major cause of leg defects (96%). Similar other studies also found trauma as the major etiological factor.<sup>2,17</sup> In another study, it was noted that all the defects were due to road traffic accidents.<sup>18</sup>

Patients with osteomyelitis were excluded from the present study. However, in a previous study, stable coverage was achieved in one patient with chronic osteomyelitis treated with a distally based adipofascial flap.<sup>16</sup>

The present study involved the left leg in 16 patients (64%). Along with lower, middle and upper-third leg defects, the other sites of defects in the present study were the ankle, tendoachilles and foot dorsum. Tendoachilles defect was covered with adipofascial flap in three patients in our study. Stable coverage was achieved in all the patients though hematoma at donor site caused complications in one case for which evacuation of hematoma and split-skin grafting was done at a later stage. Donski & Fogdestam<sup>19</sup> have mentioned raising a distally based fasciocutaneous flap based on the distal perforator of the peroneal artery to cover the Achilles tendon.

Random pattern flaps were used in 56% of the cases while perforator-based flaps were used in the remaining 44% of cases. 9 posterior tibial artery perforators and 2 peroneal artery perforators based on adipofascial flaps. Another study has found high success rate and minimal donor-site morbidity in 10 consecutive patients.<sup>20</sup>

The adipofascial flaps have the advantage of the availability of either the fatty tissue side or the fascial side, which can be insetted over the defect.<sup>16</sup> In our study, both adipose side (60%) and fascial side was (40%) used for insetting. Lin et al.<sup>21</sup> have also used both the adipose and fascial sides in their study and noted partial graft loss due to fat necrosis in three cases. Bhattacharya et al.<sup>2</sup> preferred the skin graft on the fascial surface of the flap most likely due to fat necrosis on the adipose side. Our study found equally good results with both the adipose and fascial sides.

The grafting was completed in one surgical time in all the cases in our study. Other authors reported grafting with split or full-thickness graft 5-7 days after the initial surgery.<sup>15,22</sup> Delaying skin grafting for 3 to 5 days allows an early granulating bed to develop and eliminates the problem of immediate, postoperative oozing beneath the skin graft.<sup>22</sup>

The flaps were distally based in 19 cases (76%), proximally based in 4 cases (16%) and vertically based with a transversely designed flap in 2 cases (4%). The proximally based flap cannot easily include adequate donor tissue for reconstruction in the lower part of the leg, because the soft tissue around the ankle is relatively tight and scanty.<sup>21</sup> Worseg et al.<sup>13</sup> have concluded that the vertical arrangement of the vessels supplying it ensures that any part of the lower leg can, at least in theory, be reached with the flap when raised with a paratibial or parafibular pedicle, except the heel and the Achilles tendon. In the present study, a vertically based flap was used in 2 cases. So, there is flexibility in planning this flap, in that, any location around the defect can be used as a base provided there is adequate adipose tissue.<sup>20</sup>

There were 5 smokers in the study ranging from 18 to 45 years of age and no flap or donor skin necrosis complication was found in any of them similar to another study.<sup>2</sup> There was one diabetic patient in the study who had marginal donor-site skin necrosis, which did not require further surgery. Other studies also reported partial tip necrosis, partial graft loss and partial flap necrosis among diabetic patients.<sup>21,23</sup>

Out of the 25 cases, there was partial flap necrosis in 5 patients (20%) and a total flap necrosis in 1 patient (4%). One case (4%) with partial graft loss with no flap loss healed with dressings, while 4 patients (16%) with marginal skin necrosis did not require further surgery. Two cases of partial donor skin necrosis required further split-skin grafting. Bhattacharya et al.<sup>2</sup> found marginal skin necrosis on each side of the donor site incision in three cases. The adipofascial flaps have certain inherent peculiarities including flap thinness, bleeding or hematoma, difficulties in monitoring and problems associated with skin graft take. Meland & Weimar<sup>22</sup> have demonstrated that avoidance of all external pressure is essential to maintain flap viability.

There were 2 cases in the study with complications of hematoma, one in the donor site and the other case with hematoma over the insetted adipofascial flap, beneath the skin graft. These two cases were also associated with complications of flap and donor site skin necrosis. Complications of hematoma is also mentioned in other studies<sup>15,17</sup> and proper haemostasis before closure of donor sites and flap insetting is advocated. There were no cases of venous congestion of the flaps in the study. Similar findings were also found by some other studies.<sup>15,17</sup>

No debulking procedures were required in any of the cases on follow-up. In this study, the flap has shown good contour and good donor-site scar and even in those patients who had complications and required further surgery, satisfactory results were obtained.

## CONCLUSION

Adipofascial flaps are versatile flaps due to their flexibility of flap design and the feasibility of using the flap as either a random pattern or perforator-based flap. Both fascial and adipose sides can be used for insetting depending on ease of closure and insetting requirements. It has a wide range of arc of rotation. It has reduced donor site morbidity and as thin flaps are used, the recipient sites are aesthetically better. However, the Adipofascial flaps need to be handled with care as they are delicate flaps, and if adequate adipose tissue is not left behind on the donor skin it may result in donor skin necrosis.

The adipofascial flaps are a helpful option in the armamentarium of the reconstructive surgeon, especially in small-to-medium sized lower leg defects, including the foot and tendoachilles.

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**Contribution of authors:** We declared that this work was done by the authors named in this article, and the authors will bear all liabilities about claims relating to the content of this article.

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### RESEARCH PAPER

# Functional outcome of the delayed primary and early secondary repair of Zone V flexor tendon injury of the hand

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**Background and aims:** The function of the hand and fingers is related to the normal integrity of the bones, tendons and neurovascular structures. Tendon injury often requires immediate repair. The present study was undertaken to assess the functional outcome of flexor tendon injury following delayed primary and early secondary repair of the hand's Zone V flexor tendon injury. **Methods:** In this prospective clinical study, all patients having flexor tendon injury in zone V of hand that was operated in the Department of Plastic and Reconstructive Surgery, Gauhati Medical College and Hospital, Guwahati from January 2014 to Aug 2019 were included. All the cases were repaired by the modified Kessler method, and standard early postoperative physiotherapy using Kleinert protocol was used. Total active motion percentage (TAM) of individual fingers as per The American Society for Surgery of Hand (ASSH) protocol was calculated. Hand activities were assessed according to patient satisfaction. **Results:** A total of 155 patients with zone V flexor tendon injuries were evaluated. The age at injury ranged from 9 to 62 years. The most frequent mechanism of injury was accidental injury. Delayed primary repair was performed in 58.1% of patients and early secondary repairs in 41.9% of patients. The best TAM was found in the index finger (186.9) and worst in the ring finger (175.8). Ball compression activity had the best satisfactory outcome (83.9%). **Conclusions:** Tendon repair has a better outcome with delayed primary repair than early secondary repair, according to TAM. Postoperative early mobilization results in the satisfactory outcome of the hand activities.

**Keywords:** Flexor tendon injury; Delayed Primary Repair; Early Secondary Repair; Total active motion.

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### INTRODUCTION

The hand plays a significant role in performing daily activities. The hand, the most active part of the upper limb, is also the least protected one.<sup>1</sup> The incidence of hand injuries is relatively high, and flexor tendons are commonly affected.<sup>2</sup> Hand is divided into five zones.<sup>3</sup> Zone V extends from the proximal border of the transverse carpal ligament to the musculotendinous junctions of the flexor tendon. Injury to this zone involves the median and ulnar nerves,

radial and ulnar arteries, and wrist and finger flexors.<sup>4</sup> This type of injury has been labelled as 'spaghetti wrist', 'suicide wrist', and 'full house syndrome'.<sup>3</sup> Hand injury can be caused by an accidental cut, self-inflicted or by assault resulting in loss of hand function. Proper evaluation of the injured hand should be done.

Tendon injuries require urgently care, ideally within 24 hours of injury. Most frequent cause of failure after a flexor tendon injury is adhesion formation that prevents the



tendon from gliding.<sup>5</sup> Whenever needed, tendon injury repair should be done as soon as possible but delayed repair of the tendon is done because of associated injuries or some conditions. Preoperative counselling regarding the need for physiotherapy and regular follow-up should be emphasized. On the other hand, nerve injuries related to tendon lacerations in zone V may contribute to disability, and the outcome of nerve repair can affect the overall hand function. Although injuries in this region are not infrequent, only a few studies have reported functional effects.<sup>3</sup>

Delayed primary repair is defined as repair performed within two weeks after tendon laceration, and early secondary repairs are formed between 2 and 5 weeks. Repair of tendons can be delayed for various reasons like other injuries requiring immediate surgical intervention, severe wound contamination, delayed presentation.

The present study was undertaken to assess the functional outcome of flexor tendon injury following delayed primary and early secondary repair of zone V tendon injury of hand and to see the result of early mobilization of fingers in the recovery of hand function.

## MATERIALS AND METHODS

The present research was conducted in Guwahati Medical College and Hospital in the plastic surgery department from January 2014 to August 2019. All the patients with zone 5 flexor tendon injury admitted in the plastic surgery department were included in the study. The inclusion criteria were patients clinically diagnosed with Zone 5 Flexor tendon injury, and the duration of the injury should be more than one day but less than five weeks. Patients attending the hospital before one day or after five weeks and those with a history of Hansen's disease were excluded.

It was a prospective clinical study, and prior approval for conducting the research was obtained from the institutional ethical committee of GMCH before commencing the study. Informed consent has been obtained from the participants. A detailed history of each patient was taken, along with systemic and local examinations. Necessary investigations for each procedure were done appropriately. Diagnosis of flexor tendon injury was made by history and clinical findings. The site and size of the wound were checked and recorded. Examination of the entire Flexor tendon was done and documented accordingly. The radiographs were taken to exclude fractures. Vascular status of the limb radial and ulnar and median nerves were also checked and noted. Duration and mode of injury, tendon and nerve involvement, preoperative assessment of the function (grasping and pinching) preoperative physiotherapy as necessary was done.

**Intra-operative Period:** All the patients were subjected to operation under general anaesthesia or regional anaesthesia.

All aseptic and antiseptic measures were strictly followed. Following that, draping of the operative site was done, and a tourniquet was applied and time noted. After the operation, the slab was used, and the tourniquet was removed and checked for ischemic signs. The hand was splinted at 30-degree wrist flexion and 45 degrees MCP flexion, interphalangeal joint fully extended. The hand was elevated immediately after operation to prevent oedema till primary dressing. Intravenous cephalosporin groups were administered for three days, followed by five-day oral antibiotics. Analgesics were given for two day's followed by oral analgesia and anti-inflammatory accordingly. Patients were Discharged after primary dressing on five to 7 days postoperative, and stitches were removed after 10 to 14 days postoperatively (**Fig. 2a- Fig. 2g**).

**Rehabilitation protocol:** Kleinert's dynamic elastic manual splint was applied after 24 hours continued till two weeks and physiotherapy started from day one onwards. Follow up was done twice weekly for the first two weeks. Splint modification by removing the distal interphalangeal joint guard by shortening of plaster cast up to middle phalanx and wrist flexion was extended from initial 30 degrees to 45 degrees. Weekly follow up were done for the next three weeks. Follow-up rehabilitation was done every three weeks for six months. The regular activity started after six weeks, and the patient was allowed to lift heavy objects for eight weeks in a gradual setup. Total active motion of individual fingers as per ASSH protocol was calculated as follows

Total active motion = Total active flexion - Total active extension deficit

Total active flexion = Flexion angle of DIP + PIP + MCP,  
Total extension deficit = Extension lag angle of DIP + PIP + MCP

where DIP= distal interphalangeal; PIP= proximal interphalangeal and MCP= metacarpophalangeal

TAM percentage was calculated to grade the final functional outcome as follows

TAM % = TAM of the finger × 100/260

Hand activities were assessed according to the patient satisfaction as glass holding, ball compression, key pinch and pulp to pulp touch. Complications were recorded and managed accordingly.

## RESULTS

Of 155 patients with zone V flexor tendon injuries, five were female and 150 male patients. The youngest patient was nine years, and the oldest was 62 years, with 29.7 years. Most common age group was 21-30 years. Most of the cases were of unskilled workers comprising 58.1%.

The right-sided involvements include 120 patients (77.4%),

while left-sided involvement includes 35 patients (22.6 %). The most frequent mechanism of injury was accidental injury by glass cut (100 patients), with 30 patients thrusting the hand intentionally (in anger) or by physical assault, and 25 cases were caused by road traffic accidents (**Table 1**).

**Table 1:** Mode of injury and their percentages

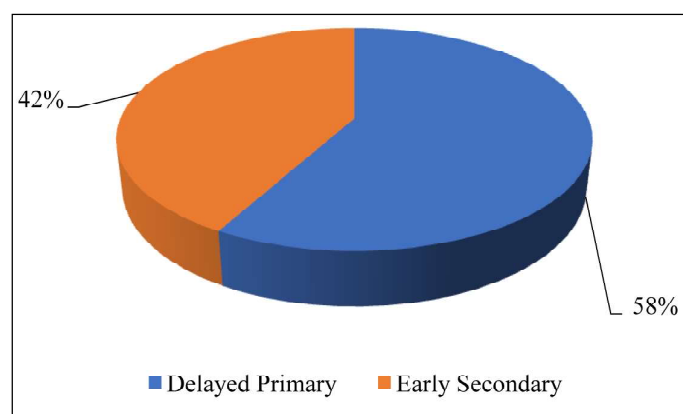
Mode of injury	Total no (%)
Glass cut	64.5%
Knife cut	19.4%
Machinery cut	16.1

The majority, 535 flexor digitorum superficialis (FDS), followed by a total of 465 flexor digitorum profundus (FDP) and 120 flexor carpi ulnaris (FCU), were found to be injured. The most common structure involved was FDS of the ring (145 patients), little finger (140patients), middle finger (135 patients), index finger (115 patients). FDP account for the second-most structure to be involved in the tendon injury. The FDP of the middle finger is the most common to be involved (130 patients), ring fingers with 125 patients, little finger 115 and index finger 95 patients (**Table2**).

**Table 2:** Structure involved

Structure involved	Total
FDS	535
FDP	465
FPL	60
FCU	120
FCR	75

The Interval between injury time the surgical intervention ranges from 5-to 28 days. Delayed primary repair was performed in 90 patients and early secondary repairs in 65 patients. (**Fig. 1**).



**Fig. 1:** Type of repair and number of cases

The average total active motions of fingers (TAM) of the hand were 181.25. The best TAM outcome was found in

index finger 186.9, and worst was in ring finger 175.8. Ball compression activity had the best satisfactory outcome with 83.9% of cases. The worst outcome was pulp to touch with 58.3% satisfactory cases compared to 25 patients (41.7%) out of 60 cases involving FPL.

Four cases had wound infection, treated conservatively with regular dressing and oral antibiotics. One patient developed wound dehiscence for which a rotational advancement flap was done. Postoperative flap necrosis was encountered in two cases for which groin flap and rotation advancement flap was done. Adhesions happened in two cases for which local massage and ultrasonography therapy was given.



**Fig. 2a** Preoperative hand cascade lost



**Fig 2b.** Pre-op Sphygmomanometer assessment



**Fig. 2c** Intraoperative finding

**Fig. 2d** Intraoperative repair**Fig. 2g** Post-op glass holding position**Fig. 2e** Postoperative hand cascade restored**Fig. 2f** Kleinert's manoeuvre

## DISCUSSION

Hand is the most mobile part of the body, and tendons play an essential part in hand functioning. The superficial location of the tendons, nerves, and vessels in the wrist jeopardizes these structures with any penetrating injury.<sup>6</sup> Laceration with broken glass is the most frequent mechanism of injury in this region.<sup>3,6</sup>

Puckett and Meyer<sup>6</sup> reviewed 38 patients with extensive volar wrist lacerations. The patients had a minimum of three and an average of eight completely transected longitudinal structures (tendon, nerve, or vessel) at the wrist. All except two had a significant nerve laceration. Protective mobilization of tendon repairs employing rubber band traction was used postoperatively. Tendon function was considered as excellent when the digital range of motion was 85%-100% of normal or finger flexion brought the fingertip within 1.0 cm of the distal palmar crease, good with 70%-84% of the normal range of motion or within 2.0 cm of the distal palmar crease, fair with 50%-69% of the normal range of motion, or poor with fixed contracture or adhesions.

Stefanich et al.<sup>7</sup> reviewed 23 patients with zone V flexor tendon repairs mobilized using a Kleinert protocol. Total active motion (TAM) values of the injured digits and the corresponding unaffected numbers were calculated, as suggested by the American Society for Surgery of the Hand (ASSH). This involved a summation of values of active flexion of the joints of a single-digit minus the summation of extension deficits in those joints. Average TAM as a percentage of the uninjured contralateral digit was given

for the whole group of 23 patients for each of the five numbers, and this value ranged from 88% to 93%. Sixteen of the 23 patients regained full digital flexion of all digits. An average PIP extension deficit of 8 and a DIP extension deficit of 4. Tenolysis was needed in 4 (17%) patients. Two patients (9%) whose compliance with hand therapy was exceptionally poor had a minimal function.

Hudson and DeJager<sup>8</sup> studied 15 patients with simultaneous lacerations of both median and ulnar nerves with flexor tendons at the wrist. The authors attributed the poor outcome mainly to sepsis and poor patient compliance. Chin et al.<sup>9</sup> reviewed 60 patients with spaghetti wrist injuries. A good to an excellent range of motion of all involved digits was observed in all 19 patients available for a follow-up examination. No patient required tenolysis.

Most of the patients were male in our study, while only 5 were female patients. This is similar to the survey done by Muhammad S. R et al.<sup>10</sup> where most of the patients were male (M: F 2.4: 1). Similar findings were also reported by Gulzar S. A et al.<sup>11</sup> and Bircan C et al.<sup>12</sup>

In our study, most of the injuries were reported in the dominant extremity (77.4%). Jaffe and Eeckesser found similar results in their research.<sup>13</sup> In another study by Rahman MT et al., right side involvement was more than the left side.<sup>14</sup>

Most of the tendon injury causes in our study were accidental, which accounts for 75 cases (48.4%). The majority of the mode of injury was glass cut injury (64.5%), followed by knife cut (19.4%) and machinery injury (16.1%). These findings are similar to the study done by Reinisch et al.,<sup>15</sup> and Rahman MT et al.<sup>14</sup>

The most common age group to be involved was in the range of 21-30 years (54.8%). This result agrees with the study done by Reinisch et al.,<sup>15</sup> and Kunzle et al.<sup>16</sup> Most of the patients were unskilled workers (58.1%). The most common structure involved was FDS, followed by FDP. Similar findings were found in another study.<sup>14</sup>

In our study, those patients who had undergone tendon repaired by delayed primary repair had a better outcome than those repaired at early secondary. Different authors did several retrospective studies on zone V flexor tendon injury. Still, their studies were primarily focused on the functional outcome of the median nerve and ulnar nerve injuries. In our study, the functional results were evaluated by patient satisfaction in performing activities like holding a glass, compressing a soft ball, key pinch, pulp to pulp pinch by thumb and the injured finger, and ability to elevate sphygmomanometer above 20 mmHg. When measuring

strength in the hand disabled subject, there are multiple advantages of a sphygmomanometer over the Jamar unit, including ready availability of a sphygmomanometer in most clinics, a soft compliant surface that may reduce minor discomfort to the injured hand during testing, and a scale with smaller increments than the Jamar Unit and, therefore, greater sensitivity to small changes in strength.<sup>17</sup>

In our study, 30 patients have developed complications, among whom 20 had wound infection at the stitch site, and 10 had flap necrosis. Gulzar SA et al.<sup>11</sup> reported 12% early postoperative infection, 8% adhesions resulting in limitation of movement at fingers, 4% rupture of tendon at the suture site due to the removal of the posterior splint 2 to 3 weeks after surgery. Another study has reported 3% tendon rupture and 3% contracture.<sup>18</sup> Elliot D et al. reported a 3-9% rupture rate.<sup>19</sup> The leading cause of complication may be delayed presentation and adhesion at the time of repair. There might be associated factors like wound contamination, the nature of wounds like laceration, avulsion with soft tissues and skin loss at the time of injury, which are significant factors responsible for postoperative complications.

**Limitation:** To evaluate the different outcomes of the tendon repairs in various time intervals, a more extensive and comparative study with a larger sample size may be undertaken.

## CONCLUSION

Tendon repair has a better Outcome with Delayed Primary Repair than Early Secondary Repair, according to the Total Active Motion Percentage Grading System of The American Society for Surgery of Hand. Postoperative early mobilization results show satisfactory outcomes of the hand activities. Wound infection was the most common complication, followed by adhesions and flap necrosis. Thus, zone-V flexor tendon repair depends on the magnitude of the injury, early repair, early mobilization, regular physiotherapy, and overall patient compliance.

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